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DYING TO KNOW: A DEMAND FOR GENUINE PUBLIC ACCESS TO CLINICAL TRIAL RESULTS DATA

*Christine D. Galbraith**

"I'm sorry, but you have cancer . . ."

Nothing can quite prepare you for hearing these words from your doctor. Especially learning of such a diagnosis in your mid-thirties, when the thought of battling a life-threatening disease hasn't even remotely crossed your mind. Advancing in one's career, building a family, buying a home—these are the typical sorts of things people my age are supposed to be doing. Confronting a possibly fatal illness like breast cancer certainly was not on any potential list of things to do I had ever imagined for myself. Nonetheless, several years ago I had no choice but to abruptly change course and begin planning a strategy to fight cancer, just like hundreds of thousands of other individuals in this country.

In fact, there are more than a quarter million women living in the United States today who were age forty or under when they were first diagnosed with breast cancer.[1] Additionally, this

* Associate Professor of Law, University of Maine School of Law; B.S. University of Illinois, 1992; J.D. University of Illinois, 1995. Many thanks to Professor Thomas Ward and Professor Marty Rogoff for their insightful comments on earlier drafts. Much appreciation to Dr. Davina Ghersi, Director of the World Health Organization's International Clinical Trials Registry Platform, as well as many of the participants at the 2008 Stanford University Law School's Intellectual Property Scholars Conference and the 2008 Tulane Law School Works in Progress Intellectual Property Colloquium for

year almost 1.5 million Americans will learn they have some form of cancer, and more than half a million will die this year from their disease.[2] Once the initial shock of receiving a diagnosis of cancer or some other life-threatening illness wears off, the next step for most individuals is to work with their doctors to develop an appropriate treatment plan. For many, including myself, this involved contemplating whether or not to enroll in some form of a clinical trial. Quite unexpectedly, however, my position as an intellectual property professor whose scholarship focuses primarily on information control, my role as a member of my university's Institutional Review Board that oversees studies involving human subjects, and my newly acquired status of "cancer patient" converged. While researching various clinical trial options for confronting my own disease, I soon became aware of an unacceptable and unnecessary risk directly shouldered by study participants, but also indirectly borne by patients generally.

I. INTRODUCTION

Each year approximately 10,000 clinical trials are conducted in the United States,[3] with more than two million individuals enrolling in these studies on an annual basis.[4] Such

extremely valuable conversations. I am also grateful to Julie Welch and Kevin Haskins for their exceptional research assistance. Additionally, I'd like to thank Dean Peter Pitegoff and the University of Maine School of Law for financial support in the form of summer research grants to complete this project. This article is dedicated to the many wonderful friends I have made on my breast cancer journey, as well as to the memories of those who have been lost to the disease.

[1] Figure based on the 2000 U.S. Census data and reported by the Young Survival Coalition. Young Survival Coalition, *Statistics*, http://www.youngsurvival.org/young-women-and-bc/statistic/ (last visited Feb. 11, 2009). Additional statistical information on breast cancer in young women has been collected and is also available. *Id.*

[2] AMERICAN CANCER SOCIETY, CANCER FACTS & FIGURES 2008 4 (2008), *available at* http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf.

[3] COMM. FOR ECON. DEV., HARNESSING OPENNESS TO TRANSFORM AMERICAN HEALTH CARE 14 (2008); FOOD & DRUG ADMIN., INNOVATION OR STAGNATION: CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS 13 (2004).

[4] *See* Wendy K. Mariner, *Human Subjects*, NAT'L L.J., May 13, 2002, at A25 (calling for the establishment of a single, independent federal entity to protect human subjects). One estimate of the number of patients needed to fill solely industry-sponsored trials

trials are an integral component of the development process for pharmaceuticals,[5] as the data generated supplies information necessary to obtain FDA approval of a new drug.[6] This approval is essential in allowing the investigative treatments to move from the research bench to the relevant patient population, potentially providing more effective medical care and protocols with more tolerable side effects. Moreover, to the extent approval is acquired, further clinical trials are often conducted to potentially identify other indications[7] for which the medication might be useful or additional patient populations that could benefit from the drug in question.[8]

Individuals register to take part in these studies for a multiplicity of reasons. Often this includes the hope that they will potentially benefit from the offered treatment if they happen to be in the arm of the trial that receives the therapy under investigation.[9] An additional rationale for most participants is the belief that the information obtained from the study will contribute to the body of scientific knowledge, ultimately assisting future patients.

Participating in a clinical trial is not, however, without risk.

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worldwide has been placed at almost twenty million in 2005, up from nearly three million in 1999. *See* Emily Anthes and Scott Allen, *US Cancer Researchers Go Abroad for Trials*, BOSTON GLOBE, December 29, 2007, at A1 (figures provided by BBK Worldwide, a US-based patient recruitment company).

[5] Clinical trials are also an important part of the process for obtaining FDA approval of medical devices and biologics, although the method of acquiring approval is slightly different. Furthermore, while the concerns raised in this article are also largely applicable to medical devices and biologics as well, for simplicity's sake I will limit my discussion of the issues to pharmaceuticals.

[6] *See infra* Part II discussing the measures required to obtain FDA approval of a new drug.

[7] For example, a pharmaceutical initially approved for treating breast cancer, may be tested to ascertain whether it also could effectively be utilized in connection with prostate cancer.

[8] This might include a drug that has initially received FDA approval for use in breast cancer patients that have a very advanced form of the disease, which might then be tested to determine whether it also would be beneficial for those individuals diagnosed at a much earlier stage.

[9] Clinical trials are frequently structured in such a way that one group of patients receives the investigational treatment, while the comparison group receives the standard therapy for the condition at issue or, in some situations, only a placebo.

As such, federal law requires researchers to provide prospective enrollees with information necessary to ideally make an educated decision regarding whether or not to take part in the study.[10] It is only after fully considering all of the relevant advantages and drawbacks to enrolling in a clinical trial can a patient truly provide the mandatory informed consent to treatment.[11] In most cases, potential study participants will be advised that taking part in the study by no means guarantees improvement in one's condition.[12] Furthermore, study investigators must supply prospective enrollees with information regarding the complete range of potential side effects, including in appropriate circumstances, disclosing that serious complications are a genuine possibility.[13] While it is impossible to completely eliminate all of the conceivable safety threats associated with participation in a clinical trial, patients are routinely exposed to a significant hazard of which they are not only unaware, but even more disturbing, one that is for the most part avoidable.

Historically, results from previous clinical studies have not been required to be made public, and drug companies have generally been exceptionally resistant to such disclosure. The pharmaceutical industry now substantially overshadows the federal government as the single greatest source of financial support for conducting clinical trials.[14] As such, these companies have taken the position that if they are funding the research, the data produced should consequently be deemed their property, protectable through patent, trade secret, and contract law.[15] Additionally, the FDA has generally supported this view, and the courts by and large have similarly agreed.[16]

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[10] 21 C.F.R. § 50.20 (2007).

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] The vast majority of clinical trials are now funded by for-profit companies. *See* Shankar Vedantam, *Drugmakers Prefer Silence on Test Data*, WASH. POST, July 6, 2004, at A1.

[15] *See infra* Part VI discussing these legal arguments.

[16] *See infra* Part II discussing FDA regulations which prohibit the disclosure of proprietary information.

Accordingly, only a small fraction of trial outcomes are eventually published in medical journals or in some other peer-reviewed format.[17] Moreover, research has shown that most of the pieces ultimately published tend to be about trials that demonstrate the treatment under investigation was in fact superior as compared to the traditional therapy or placebo.[18] This propensity for journals including articles on clinical studies with positive results is frequently referred to as "publication bias."[19]

From a practical standpoint, this means that future studies are generally not informed by previous research. This is particularly true of clinical trials that have negative outcomes. As a result, additional studies involving identical or similar treatment regimes may be repeated without the knowledge of patients, doctors, or other researchers. Such a possibility is not merely theoretical as, for example, competitors often develop and test molecular entities in the same class with comparable mechanisms of action or, as often the case may be, inaction.

Consequently, when clinical investigators replicate trials that have previously been shown to be ineffective or even harmful, human subjects are placed at considerable risk. By failing to release pertinent information regarding the results of earlier trials, study participants are often left to shoulder the significant danger posed by the investigational treatment without the potential for any benefit, in contradiction to commonly recognized ethical standards. Furthermore, to the extent results from clinical trials never enter the public domain, the compelling contribution of these patients becomes essentially meaningless. This has prompted many in the worldwide medical community to characterize this failure to publish the results as a form of scientific misconduct and a

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[17] The peer-review process is often extolled by the medical and scientific community as the ideal method of publishing and is the one used most by the leading journals. This model generally allows for review of the research data and the article itself by other experts in the field prior to publication. Nonetheless, while there are reasons to believe this may be the preferred approach, the peer-review process does not completely guarantee the accuracy of the information contained within the published piece.

[18] *See infra* Part VII reviewing the wide body of research devoted to this topic.

[19] *See infra* Part VII examining publication bias and its various implications.

violation of ethical principles.[20] As an editorial in the *New England Journal of Medicine* so aptly stated, "When patients put themselves at risk to participate in clinical trials, they do so with the tacit understanding that their risk is part of the public record, not merely the secret record of the sponsor."[21]

Additionally, the failure to disclose study results not only impacts clinical trial participants, but the health of the general public may be put in jeopardy as well. For drugs that have received FDA approval, post-market clinical trials investigating new uses of the medication often reveal important information concerning side effects and related adverse complications with the treatment. To the extent that prescribing physicians do not have this essential data, they could inadvertently be putting their patients at serious risk by continuing to recommend the medication.

Over the past few years, numerous scandals in the drug industry illustrate that concealing unfavorable research results is far from an isolated practice.[22] Cases have implicated many of the leading pharmaceutical companies and involved such blockbuster drugs as Paxil and Vioxx, to name just a few.[23] In a quest to boost sales and increase corporate profits, the temptation to hide or selectively disclose clinical trial data has proven to be too much.

Amid mounting claims of misconduct by drug manufacturers and increasing concern regarding the FDA's role in the various controversies, both the Senate and House held a number of hearings on the issue.[24] Congress responded to the

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[20] See infra Part VII further examining this position. *See* Karmela Krleža-Jerić et al., Principles for International Registration of Protocol Information and Results from Human Trials of Health Related Interventions: Ottawa Statement (Part 1), 330 BRITISH MED. J. 956 (2005); World Med. Ass'n, World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, 284 JAMA 3043 (2000).

[21] Jeffrey M. Drazen & Alastair J.J. Wood, *Trial Registration Report Card*, 353 NEW ENG. J. MED. 2809, 2810 (2005).

[22] *See infra* Part III providing representative examples of several well-documented cases of such intentional deception.

[23] *See infra* Part III reviewing these cases.

[24] *See Publication and Disclosure Issues in Antidepressant Pediatric Clinical Trials: Hearing Before the H. Comm. on Energy and Commerce*, 108th Cong. 26 (2004)

intensifying pressure by the medical community, patient rights advocates, and the general public[25] by enacting federal legislation in late 2007 that purportedly provided extensive transparency regarding clinical trials by creating a clinical trial results database.[26] One of the bill's sponsors, in extolling the virtues of the measure on the Senate floor, asserted that as a result of the new legislation "the public will [now] know about each trial underway, and will be able to review its results."[27] Unfortunately, this characterization is far from accurate.

In actuality, the results of only a very small minority of the trials conducted involving human subjects will require disclosure under the Act as currently configured. This is due to the fact that with some minor exceptions, only data on later stage[28] clinical trials must be released, and this is *only if* the treatment under investigation actually receives FDA approval.[29] As even the FDA itself has acknowledged, "[T]he vast majority of investigational products that enter clinical trials fail."[30] This scarcity of success is frequently attributable to a finding that the

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[hereinafter Antidepressants Hearing]; *FDA, Merck and Vioxx: Putting Patient Safety First: Hearing Before the S. Comm. on Finance,* 108th Cong. (2004) [hereinafter Vioxx Hearing]; *Ensuring Drug Safety: Where Do We Go From Here?: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions,* 109th Cong. (2005) [hereinafter Drug Safety Hearing]; *FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 109th Cong (2005) [hereinafter FDA Approval Process Hearing]; *Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation: Before the S. Comm. on Health, Education, Labor, and Pensions*, 110th Cong. (2006) [hereinafter FDA Improvement and Innovation Hearing].

[25] *See* Fiona Godlee, *An International Standard for Disclosure of Clinical Trial Information*, 330 BRITISH MED. J. 7502 (2005) (discussing a recent survey that found only a quarter of Americans were of the opinion that the pharmaceutical industry was doing a good job; interestingly, such a low approval rating is in line with the public's perception of the tobacco industry.).

[26] Food & Drug Admin. Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at 21 USC §§ 301 *et seq.*).

[27] 153 CONG. REC. S11,831 (Sept. 20, 2007) (statement of Sen. Kennedy).

[28] Results from Phase I studies do not have to be reported. *See* Section II *infra* reviewing the various phases of clinical trials and Section VII *infra* discussing why the disclosure of Phase I trial data should be mandatory.

[29] 21 U.S.C. § 355(j)(1)(A)(iii) (2008).

[30] FOOD & DRUG ADMIN., INNOVATION OR STAGNATION: CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS 6 (2004). *available at* http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html.

compound at issue is either ineffective or has significant safety problems, such as severe side effects.[31] As a result, a new drug entering the initial phase of trials involving human subjects is estimated to have only an eight-percent chance of ever obtaining federal approval and ultimately reaching the market.[32]

This legislation therefore allows a tremendous amount of information to remain hidden away, falling far short of providing meaningful statutory reform. Studies which are unsuccessful may continue to go unreported with unfavorable results concealed. Ironically, most of the scandals which precipitated the push for reforms regarding data disclosure in the first place could still easily occur, as the supposed safeguards mandating release still would not require the information at issue in those situations to be made publicly available.[33]

The only thing the statute truly appears to accomplish is to supply a means to potentially placate the public without displeasing the pharmaceutical industry. The drug companies continue to cite a wide variety of rather unconvincing arguments as to why any further disclosure would be completely unfeasible.[34] Nonetheless, even assuming the possible merit of these contentions, it is not at all clear why the pharmaceutical industry's claims should take precedence.

Incomplete release of study results not only impedes scientific research, but of even greater concern, needlessly places human lives in jeopardy. Such a state of affairs is wholly unacceptable. Therefore, this article calls for comprehensive disclosure of meaningful clinical trial results data from all studies, including the underlying raw data, regardless of whether FDA approval is ever obtained or even sought. This would offer true transformation of the current system, as well as

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[31] *Id.* at 7.

[32] *Id.*

[33] *See infra* Part V discussing the numerous shortfalls of the Act and how it fails to adequately protect the public from future problems similar to those which have surfaced over the past few years in the pharmaceutical industry.

[34] *See infra* Part VI reviewing the various arguments put forth by the pharmaceutical industry and examining their claimed merit.

ensure the risk endured by the courageous men and women that volunteer for clinical trials is not worthless.

This article begins in Part II by examining the important role clinical trials play in the FDA approval process. This section also reviews the regulations and policies that prohibit the FDA from disclosing the vast majority of relevant data included in the pharmaceutical company's application due to the fact that much of the material is classified as proprietary information. Part III discusses a number of well-documented controversies in the pharmaceutical industry involving the concealment or misrepresentation of clinical trial results data, including the FDA's actions in connection with these cases. Part IV briefly reviews the legislative precursors to the Food and Drug Administration Modernization Act ("FDAMA") which required the creation of a clinical trials database that eventually became law on September 27, 2007. Part V presents a comprehensive analysis of the FDAMA, discussing the numerous ways in which the statute is deficient. Part VI evaluates the many claims advanced by drug companies to support their position against expanded disclosure of results information. Included in this section is an analysis of the various legal constructs that drug makers have argued grant them an ability to control information regarding clinical trial results data, namely trade secret, contract, and patent law. Lastly, Part VII examines the compelling arguments that lend significant support to a demand for further release of clinical trial data.

II. THE SIGNIFICANT ROLE CLINICAL TRIALS PLAY IN THE FDA APPROVAL PROCESS

The federal government did not play an active part in the regulation of pharmaceuticals until 1906 when Congress passed the Pure Food and Drug Act.[35] This statute prohibited the sale of misbranded and adulterated drugs.[36] In 1938, the Federal

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[35] Pure Food & Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (repealed by the Food, Drug, and Cosmetic Act of 1938).

[36] *Id.*

Food, Drug and Cosmetic Act ("FDCA") repealed the Pure Food and Drug Act.[37] The FDCA required the FDA for the first time to evaluate studies conducted by manufacturers to determine if the drug was safe for its intended use prior to commercial distribution of the medication.[38] In 1962, the FDCA was amended, mandating that a drug's sponsor not only prove a medication's safety as previously required, but also now validate its efficacy.[39] This was to be demonstrated with evidence from adequate and well-controlled clinical trials.[40]

Such a prerequisite continues today, as a pharmaceutical company must substantiate its claims that a drug is safe and effective to the FDA through studies involving human subjects before the treatment is approved for marketing.[41] However, the FDA drug approval process doesn't allow for immediate testing on human beings. Instead, preclinical evidence must first be gathered. Typically, this commences with scientific researchers attempting to search for and identify chemical entities that show potential for treating or even curing a particular disease.[42] Once such a compound has been ascertained, customarily the next step is to proceed with either extensive laboratory testing, or as more often the case, studies involving animals.[43] If this research appears promising, a pharmaceutical maker will often continue on with the approval process by filing an investigational new drug application ("IND").[44]

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[37] Federal Food, Drug, & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[38] *Id.*

[39] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

[40] *Id.*

[41] 21 U.S.C. § 355(d)(5) (2008). Pharmaceutical manufacturers must demonstrate "substantial evidence" of efficacy. *See* discussion *infra* Part II.A further discussing the FDCA's definition of this requirement and the FDA's interpretation thereof.

[42] U.S. GOV. ACCOUNTABILITY OFFICE, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 6 (2006).

[43] *Id.*

[44] The pharmaceutical industry estimates that on average only five in every 10,000 compounds successfully complete this preclinical testing. *See id.*

A. Investigational New Drug Application (IND)

A pharmaceutical company may not begin clinical trials involving the administration of an investigational drug to human subjects until an IND is submitted.[45] The primary purpose of an IND is to supply the FDA with sufficient information from earlier studies involving laboratory animals or in vitro laboratory testing to make a determination as to whether or not it is reasonably safe to proceed with trials involving human beings.[46] Additionally, the applicant must provide assurances that all proposed studies involving human subjects will first be approved and then continually reviewed by an appropriately constituted Institutional Review Board ("IRB").[47] While the FDA does not provide an official approval of the application, the planned studies may be subject to a clinical hold by the agency, namely an order to delay the anticipated clinical investigation until any problems are resolved regarding the intended protocol.[48] More often than not, the proposed investigational plan does not raise concerns. Accordingly, the IND will go into effect thirty days after the FDA receives the application, at which point the drug company may proceed with clinical trials involving human subjects.[49]

Clinical investigations of pharmaceuticals that have not previously undergone human testing are typically divided into three principal stages.[50] While these three phases usually are conducted sequentially, in some cases they may in fact overlap.[51] The earliest introduction of an investigational new drug in human subjects occurs in Phase I studies.[52] Such trials are

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[45] 21 C.F.R. § 312.20(b) (2008).

[46] 21 C.F.R. § 312.22 (2008).

[47] 21 C.F.R. § 312.66 (2008). The requirements for the composition, operation, and responsibilities of an IRB that reviews clinical trials regulated by the FDA is found in 21 C.F.R. § 56 (2008). Failure to obtain IRB approval of research protocols may result in an inability to submit the findings from such trials to the FDA. *See* 21 C.F.R. § 56.103(b) (2008).

[48] 21 C.F.R. § 312.42 (2008).

[49] 21 C.F.R. § 312.40 (2008).

[50] 21 C.F.R. § 312.21 (2008).

[51] *Id.*

[52] 21 C.F.R. § 312.21(a)(1) (2008).

generally comprised of twenty to eighty healthy volunteers.[53] However, in studies examining treatments that are expected to have significant toxicities, such as chemotherapy agents, only patients suffering from cancer will be allowed to participate in the clinical trial. The primary objective of Phase I studies is to determine appropriate dosing levels for the drug in question, as well as identify possible side effects.[54]

Phase II studies usually include no more than several hundred subjects.[55] Individuals involved in this phase, ordinarily consist solely of persons with the disease or condition under investigation.[56] These clinical trials are conducted primarily to evaluate the effectiveness of the pharmaceutical at issue, although side effects and risks associated with the drug continue to be monitored.[57]

In Phase III trials, the medication is normally tested on several hundred to several thousand patients.[58] Similar to Phase II trials, the subjects in this stage also have been diagnosed with the disorder at issue in the study. Such trials are performed to collect further information about efficacy and safety which will then be used to determine the critical overall risk-benefit ratio of the investigative treatment.[59] Additionally, the studies provide the data that will form the basis for physician labeling of the medication.[60] Phase III trials are typically the principal studies upon which the FDA relies in determining whether or not approval of the pharmaceutical is appropriate.[61]

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[53] *Id.*

[54] 21 C.F.R. § 312.21(a) (2008).

[55] 21 C.F.R. § 312.21(b) (2008).

[56] *Id.*

[57] *Id.*

[58] 21 C.F.R. § 312.21(c) (2008).

[59] *Id.*

[60] *Id.*

[61] The FDA can utilizes its authority to make approval of an NDA conditional on the applicant's agreement to conduct post-marketing clinical trials, often referred to as Phase IV studies. Such studies are often employed to investigate issues concerning the drug's risks, benefits, and optimal use. 21 C.F.R. § 312.85 (2008).

B. New Drug Application (NDA)

If the pharmaceutical company believes the evidence obtained from completed clinical trials demonstrates that the investigational drug shows potential for approval, the next step is to file a New Drug Application ("NDA") with the FDA.[62] The NDA is designed to provide detailed information regarding the data obtained while the IND was in effect.[63] Accordingly, the application must contain reports of every clinical trial sponsored by the applicant involving the medication, regardless of outcome.[64] Additionally, all relevant information about the drug that has been acquired by the applicant from any source also needs to be provided to the FDA.[65]

The FDA will analyze the information provided to determine whether or not there is adequate evidence to establish that the pharmaceutical is safe and effective for the conditions of use advanced by the applicant.[66] In doing so, the FDA conducts a risk-benefit analysis in order to ascertain whether the advantages of the medication outweigh the potential for harm.[67] With regard to determining efficacy, the standard utilized by the FDA is that of "substantial effectiveness."[68] This term was defined by the 1962 amendments to the FDCA as follows:

> [E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or

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[62] 21 U.S.C. § 355(b) (2008); 21 C.F.R. § 314 (2008).

[63] 21 C.F.R. § 314 (2008).

[64] 21 C.F.R. § 314.50 (2008).

[65] *Id.*

[66] 21 U.S.C. § 355(d) (2008); 21 C.F.R. § 314.125 (2008).

[67] 21 C.F.R. § 312.84 (2008).

[68] 21 U.S.C. § 355(d) (2008); 21 C.F.R. § 314 (2008).

suggested in the labeling or proposed labeling thereof.[69]

This definition has generated considerable debate, especially concerning the amount of data necessary to establish effectiveness.[70] Traditionally, the FDA took the position that Congress intended this to require results from at least two clinical trials that demonstrate the investigative drug is superior to a placebo or the conventional treatment.[71] However, in 1997, as part of the FDA Modernization Act, the FDCA was amended to clarify that positive results from a single trial may be adequate.[72]

Conversely, there is no established number of negative trials that will be grounds for rejecting the application. In fact, there may be extensive evidence from numerous clinical studies of a drug ultimately approved by the FDA that shows the medication not only performed similarly to the control treatment, but actually was inferior.[73] For example, an analysis of clinical studies of antidepressants found that the makers of Prozac had to conduct five trials to obtain two that were positive, while the manufacturers of Paxil and Zoloft needed to sponsor even more.[74] Such trial results historically have not been disclosed by the FDA.[75] Similarly, when studies reveal significant toxicity, this evidence also has not generally been

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[69] 21 U.S.C. § 355(b) (2008).

[70] FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUGS AND BIOLOGICAL PRODUCTS 3 (1998).

[71] *Id.*

[72] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 103 (codified as 21 U.S.C. § 355(d) (2008)). The amended provision now states as follows: "If the Secretary [of Health and Human Services] determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence. . . ." § 355.

[73] *See infra* Part III reviewing the negative clinical trial evidence associated with the many of the drugs involved in recent scandals.

[74] A. Khan et al., *Severity of Depression and Response to Anti-Depressants and Placebo: An Analysis of the Food and Drug Administration Database*, 22 J. CLINICAL PSYCHOPHARMACOLOGY 40, 40-45 (2002).

[75] *See infra* Part V examining how this disclosure policy was altered by the FDAAA, as well as discussing why these changes are not sufficient.

publicly released by the agency.[76]

C. Confidentiality of Information Submitted to FDA

Traditionally, FDA disclosure of materials submitted to the agency has been exceptionally limited. Data that is classifiable as trade secrets[77] or confidential commercial information[78] typically cannot be revealed to the general public, unless the applicant grants permission to such dissemination.[79] In fact, even the mere existence of an IND or NDA filing may not generally be disclosed, unless this has been previously divulged or acknowledged by the applicant.[80] Furthermore, under the Trade Secrets Act, disclosure of this type of data by an FDA employee constitutes a criminal offense.[81]

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[76] *Id.*

[77] 21 C.F.R. § 20.61(a) (2008) defines a trade secret as consisting of "any commercially valuable plan, formula, process, or device that is used for the marking, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *See also infra* Part VI evaluating the strength of claims by pharmaceutical companies that clinical trials results data constitutes a trade secret.

[78] 21 C.F.R. § 20.61(b) (2008) defines confidential commercial information as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." *See also infra* Part VI examining the validity of drug industry arguments that clinical trials results data should be classified as proprietary information.

[79] 21 C.F.R. § 20.61(c) (2008).

[80] 21 C.F.R. § 312.130(a) (2008) (non-disclosure of IND filing); 21 C.F.R. § 314.430(b) (2008) (NDA filing will not be revealed before an approvable letter has been sent to the applicant).

[81] 18 U.S.C. § 1905 (2008) provides:

> Whoever, being an officer or employee of the United States or of any department or agency thereof, . . . publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; . . . shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.

See also infra Part VI examining the strength of arguments by the drug industry and the

These policies have been the source of immense frustration, as illustrated by testimony provided by a patient advocate in connection with a Senate hearing on the FDA approval process who stated as follows: "The FDA is probably one of the most secretive government agencies that any consumer will ever have to deal with. Virtually everything about a drug is considered proprietary. Agency officials will not talk with anyone about the drug unless the manufacturer gives them permission to do so."[82]

Although certainly subject to debate,[83] clinical trial results have historically been categorized as trade secrets or confidential commercial information by the FDA. Consequently, such study data may not be disclosed without the consent of the pharmaceutical company that originally provided the information to the agency.[84] Additionally, adverse events[85] reports required to be submitted by the drug manufacturer

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general concurrence of the FDA that such information comprises trade secrets.

[82] *FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 109th Cong. 55-60 (2005) (statement of Abbey S. Meyers, President of the National Organization for Rare Disorders).

[83] *See infra* Part VI discussing why the FDA's conclusions regarding the classification of clinical trial data as trade secrets or confidential commercial information is arguably improper.

[84] *See infra* Part V discussing the FDAAA and its arguably slight impact on the FDA's general policies regarding the reporting of clinical trials results data.

[85] An "adverse event" is defined by FDA regulations as "[a]ny adverse experience associated with the use of the drug that is both serious and unexpected," as well as, "[a]ny finding from tests in laboratory animals that suggests a significant risk for human subjects." 21 C.F.R. § 312.32(c) (2008). An adverse experience is "serious" if it "results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect." 21 C.F.R. § 312.32(a) (2008). Additionally, an adverse experience is "unexpected" to the extent that the incident is such that:

> The specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended.

21 C.F.R. § 312.32(a) (2008). Furthermore, the regulation provides that "unexpected" refers to an adverse drug experience that has not been previously observed (e.g., included in the investigator brochure) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product. 21 C.F.R. § 312.32(a) (2008).

concerning harms experienced by clinical trial participants associated with the use of the medication are treated similarly.[86] As a result, the FDA has traditionally refused to release this critical information for public scrutiny on the grounds it is proprietary.[87]

III. Allegations of Suppression and Misrepresentation of Clinical Trial Data in the Drug Industry

Virtually all of the major pharmaceutical companies have come under scrutiny in the past few years over claims they concealed unfavorable clinical trial findings or distorted the results of study information that they voluntarily chose to publicly release. The FDA's conduct has also been called into question in connection with many of these controversies, as evidence began to emerge that the agency had intentionally blocked or delayed warnings regarding use of the medications at issue from reaching the public. Additionally, these cases serve to highlight the numerous deficiencies in the law regarding the reporting of clinical trial data which allows drug manufacturers and the FDA to largely control all disclosure. As such, two of the most publicized controversies are reviewed below in more detail to provide context for the argument that increased access to study results is crucial.

A. Anti-Depressants and Pediatric Patients

1. GlaxoSmithKline's Paxil

GlaxoSmithKline ("GSK"), one of the world's largest drug manufacturers, produces and sells the drug paroxetine. This medication is marketed in the United States as Paxil[88] and has

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[86] *See infra* Parts VI-VII examining the various arguments in favor and against further public disclosure of such information, as well as a related discussion concerning the definitional and organizational problems associated with the reporting system itself.

[87] *See infra* Part VII discussing the problems associated with such a policy. *See also infra* Part V examining the negligible changes to these rules by the FDAAA.

[88] This drug is also sold under the trade name Seroxat in many countries outside the United States, including Britain.

been approved by the FDA for treating a variety of indications, including depression, anxiety, and obsessive compulsive disorder in adults.[89] This pharmaceutical has not, however, received approval for use in children or adolescents.[90] Nonetheless, approximately 2.1 million prescriptions were written for use of the medication in this pediatric population of patients in a single year alone.[91] Such conduct by physicians is permitted through a common practice referred to as "off-label" prescribing.[92] While the FDA approves a drug for particular conditions and a specific type of patient population, doctors are allowed to prescribe FDA-approved medications for other indications if a physician determines it is appropriate.[93] In order to reach such a conclusion, a doctor usually must rely on his or her assessment of information received from other sources in order to perform a risk-benefit analysis of the potential treatment.[94]

On June 2, 2004, then New York Attorney General Eliot Spitzer filed suit against GSK alleging that the company misrepresented safety and efficacy data by publicizing positive information about the use of Paxil in children and adolescents while withholding or misrepresenting other negative clinical trial findings.[95] GSK had conducted at least five studies examining the use of Paxil for pediatric patients.[96] The results of these studies not only failed to demonstrate efficacy, but also suggested the medication potentially increased the risk of suicidal thinking and acts.[97] Nonetheless, GSK implemented an aggressive marketing campaign to promote the questionable

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[89] Complaint at ¶ 2, The People of the State of New York by Eliot Spitzer v. GlaxoSmithKline, PLC (N.Y. Sup. Ct. June 2, 2004), *available at* http://news.findlaw.com/cnn/docs/glaxo/nyagglaxo60204cmp.pdf [hereinafter GSK Complaint].

[90] *Id.* at ¶ 2.

[91] *Id.* at ¶ 3.

[92] *Id.* at ¶ 2.

[93] *Id.* at ¶ 2.

[94] *Id.* at ¶¶ 12, 13.

[95] *Id.* at ¶¶ 4, 30.

[96] *Id.* at ¶¶ 15-18.

[97] *Id.* at ¶¶ 19-30.

benefits of the drug in children and adolescents.[98]

A confidential, internal GSK memorandum provided employees guidance on how "[t]o effectively manage the dissemination of these data in order to minimise [sic] any potential negative commercial impact."[99] This was necessary, since according to the document, the clinical trial results were "insufficiently robust" and would fail to support approval of an application for expanded use of Paxil to treat pediatric depression.[100] Additionally, the memo recommended publication of a full medical journal article only on the single study which contained some favorable conclusions.[101] However, it further cautioned that "[i]t would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine."[102] GSK also allegedly repeatedly misrepresented the safety and efficacy outcomes from the studies to its sales representatives who consequently promoted the medication to physicians, as well as to doctors directly through the "Medical Information Letters" the company distributed.[103]

Furthermore, after the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA")[104] advised that paroxetine should not be used by children and adolescents to treat depression,[105] GSK issued a press release in Britain in which the company admitted that clinical studies revealed "a difference between [paroxetine] and placebo in terms of suicidal

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[98] *Id.* at ¶ 30.

[99] *Id.* at ¶ 31.

[100] Wayne Kondro & Barbara Sibbald, *Drug Company Experts Advised Staff to Withhold Data about SSRI Use in Children*, 170 CAN. MED. ASS'N. J. 783, 783 (2004) (discussing the contents of the GSK internal document, which was obtained and consequently published by the journal).

[101] GSK Complaint, *supra* note 89, at ¶ 32.

[102] Kondro & Sibbald, *supra* note 100, at 783.

[103] GSK Complaint, *supra* note 89, at ¶¶ 37-39, 41-45.

[104] The MHRA is the British equivalent of the FDA in the United States.

[105] MED. AND HEALTHCARE PRODUCTS REGULATORY AGENCY, SAFETY REVIEW OF ANTIDEPRESSANTS USED BY CHILDREN COMPLETED (2003), *available at* http://www.mhra.gov.uk/newscentre/pressreleases/CON002045 [hereinafter MHRA]. Following the MHRA's decision, the Irish Medicines Board also issued a similar directive. GSK Complaint, *supra* note 89, at ¶ 49.

thinking or attempts, particularly in adolescents."[106] However, a few days later GSK issued a very different statement in the United States in which it merely noted that "there is no evidence that Paxil is associated with an increased risk of suicidal thinking or acts in adults" and that "not a single person [who participated in the pediatric paroxetine trials] committed suicide."[107]

The New York Attorney General's complaint charged that by selectively disclosing information about the clinical trials, GSK misled and deceived physicians.[108] By creating the false impression that the safety and efficacy evidence in GSK's control was incontrovertible, the company deprived those in the medical community of the materials necessary to properly evaluate the risks and benefits of prescribing Paxil to children and adolescents.[109] GSK publicly responded to these contentions by issuing a statement declaring it had "acted responsibly in conducting clinical studies in pediatric patients and disseminating data from those studies."[110] Furthermore, the company stated that all trial data had "been made available to the FDA . . . and regulatory agencies worldwide."[111]

Nonetheless, less than three months after the lawsuit was originally filed, GSK settled the case.[112] As part of the Agreement, GSK was required to establish an online "Clinical Trials Register" to distribute summary information from company sponsored studies of FDA-approved drugs.[113] Additionally, GSK promised to make certain that all

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[106] GSK Complaint, *supra* note 89, at ¶¶ 49-51.

[107] *Id.* at ¶ 61.

[108] *Id.* at ¶ 63.

[109] *Id.* at ¶¶ 62, 63.

[110] Owen Dyer, *GlaxoSmithKline Faces US Lawsuit Over Concealment of Trial Results*, 328 BRITISH MED. J. 1395, 1395 (2004) (article contains a reprint of the complete statement).

[111] *Id.*

[112] Press Release, Office of N.Y. State Att'y Gen. Eliot Spitzer, Settlement Sets New Standard for Release of Drug Information (Aug. 26, 2004), *available at* http://www.oag.state.ny.us/media_center/2004/aug/aug26a_04.html (last visited Jan. 19, 2009) [hereinafter N.Y. State Att'y Gen.].

[113] *Id.* *See supra* Section IV examining the many deficiencies of such company sponsored databases.

communications it provided to the medical community regarding off-label uses of drugs would "fairly and accurately reflect the safety and efficacy data from clinical studies."[114] Lastly, the company agreed to pay $2.5 million representing "disgorgement and costs" to the State of New York.[115] While the New York State Attorney General's case against GSK may have been resolved, the controversy associated with the use of antidepressants in the pediatric population for psychiatric disorders had by no means come to a conclusion.

2. Further Scrutiny of Other Manufacturers of Psychiatric Medications

Less than a month after the settlement with GSK, the New York State Attorney General's office announced in early September of 2004 that it had reached a separate agreement with Forest Laboratories, Inc. ("Forest Labs").[116] Forest Labs manufactures and distributes anti-depressants under the brand names Lexapro and Celexa.[117] As with GSK's Paxil, the medications are only FDA approved for treating psychiatric conditions in adults, but were nonetheless regularly prescribed off-label for children and adolescents. The Attorney General had questioned whether the company had concealed information regarding the safety and efficacy of its drug.[118] Forest Labs responded to the inquiry by agreeing to publicly disclose clinical studies concerning the use of Lexapro and Celexa in pediatric populations, as well as posting online the results from all future company-sponsored studies of approved medications.[119]

Additionally, the New York State Attorney General's Office also revealed in the same statement that leading

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[114] N.Y. State Att'y Gen., *supra* note 112.

[115] *Id.*

[116] Press Release, Office of N.Y. State Att'y Gen. Eliot Spitzer, Forest Labs to Establish Clinical Trials Registry (Sept. 7, 2004), *available at* http://www.oag.state.ny.us/media_center/2004/sep/sep7b_04.html (last visited Feb. 4, 2009).

[117] *Id.*

[118] *Id.*

[119] *Id.*

pharmaceutical companies Eli Lilly and Merck had agreed to publicly disclose certain clinical trial information.[120] Eli Lilly markets its antidepressants under the brand names Prozac and Cymbalta, while Merck sells its medication as Vivactil.[121] Both of these companies were allegedly under scrutiny as well in connection with their selective disclosure of clinical trial data.

3. Questionable Conduct by the FDA

The FDA did not publicly acknowledge that antidepressant use by pediatric patients posed an increased risk of suicidal thoughts and actions until mid-September of 2004.[122] The following month, the agency issued a public health advisory regarding the possible dangers associated with the use of the drugs.[123] Additionally, the FDA directed that all manufacturers of antidepressant medications place a "black box" warning on their products, although the agency did not expressly forbid doctors from continuing to prescribe these drugs for their younger patients.[124] Despite taking such actions, the FDA came under intense scrutiny concerning its handling of the antidepressant controversy.

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[120] *Id.*

[121] While it seems fairly clear the inquiry into Eli Lilly was with regard to its conduct in relation to the promotion of Prozac and possibly Cymbalta, it is not completely evident that Merck was under scrutiny concerning Vivactil. It is possible that the New York State Attorney General's Office may have been focusing their investigation on Merck's lack of disclosure surrounding its distribution of its Vioxx-brand pain reliever, although at the time of the Office's press release, the company had not yet received the preliminary results from a clinical trial which eventually compelled Merck to withdraw Vioxx from the market.

[122] Gardiner Harris, *FDA Links Drugs to Being Suicidal,* N.Y. TIMES, Sept. 14, 2004, at A1.

[123] FOOD & DRUG ADMIN., PUBLIC HEALTH ADVISORY: SUICIDALITY IN CHILDREN AND ADOLESCENTS BEING TREATED WITH ANTIDEPRESSANT MEDICATIONS (2004), *available at* http://www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm.

[124] *Id.* A "black box" warning is the most serious warning placed on the label of a prescription drug. Several years later, the FDA would expand the black box warnings to also include young adults ages 18 to 24 during initial treatment with the antidepressants. *See* FOOD & DRUG ADMIN., FDA PROPOSES NEW WARNINGS ABOUT SUICIDAL THINKING, BEHAVIOR IN YOUNG ADULTS WHO TAKE ANTIDEPRESSANT MEDICATIONS (2007), *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01624.html.

This was due to the fact that questions continued to arise over the adequacy of the agency's response, particularly whether it came quickly enough to prevent public harm. For example, almost a year earlier British regulators had not only informed the public about the perceptible risks associated with the antidepressant medications evidenced through clinical trial data, but also generally prohibited further pediatric use of the drugs.[125] In response, a scathing editorial in the medical journal *The Lancet* declared that the FDA appears to have "failed to act appropriately on information provided to them that these drugs were both ineffective and harmful in children."[126] This characterization would seem even more apropos as additional evidence concerning the agency's conduct came to light.

In early 2004, one of the FDA's own drug safety analysts, Dr. Andrew Mosholder, completed his review of data from numerous clinical trials and concluded that antidepressant medications were clearly associated with an increased risk of suicidal behavior.[127] Mosholder found that pediatric patients were almost twice as likely to suffer a serious suicide-related event.[128] However, agency officials expressed skepticism over the reliability of his findings due to concerns regarding whether the sponsoring companies of the studies had classified suicidal cases properly.[129] Thereupon, they ordered a second examination of the trial data by another FDA scientist.[130]

Dr. Mosholder responded in a memo to this proposal by cautioning that an additional analysis was unwarranted since "it is unlikely that the new information will alter the basic finding of an association of . . . serious suicide-related events

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[125] MHRA, *supra* note 105. One of the few exceptions was Fluoxetine, marketed under the brand name Prozac, which according to the agency "appears to have a positive balance of risks and benefits in the treatment of depressive illness in the under 18s." *Id.*

[126] *Depressing Research*, 363 LANCET 1335, 1335 (2004).

[127] Shankar Vedantam, *FDA Study Confirms Antidepressant Risks*, WASH. POST, Aug. 10, 2004, at A6. *See* Antidepressants Hearing, *supra* note 24.

[128] Vedantam, *supra* note 127, at A6.

[129] *Id.*

[130] *Id.* *See* Susan Okie, *What Ails the FDA?*, 352 NEW ENG. J. MED. 1063, 1063 (2005).

with active treatment."[131] Moreover, he urged the FDA in the meantime to officially discourage the use of antidepressants in children; however, the agency refused to do so.[132]

Instead, the FDA concealed his findings and prevented him from sharing his analysis with an FDA advisory committee convened in February of 2004 to investigate continuing public concerns surrounding the safety of the drugs.[133] Approximately six months later, however, the additional staff analysis requested by agency officials confirmed Mosholder's original conclusions.[134]

The continuing reluctance of the FDA to provide information to the public regarding the use of antidepressants in children and adolescents prompted a congressional hearing by the House Committee on Energy and Commerce in September of 2004.[135] Testimony revealed that the FDA had repeatedly restrained pharmaceutical companies from publicly disclosing to physicians that clinical trials had demonstrated the drugs had performed no better than the placebos, as well as additional negative findings.[136] The vice-president of pharmaceutical giant Pfizer recounted how the company had planned to include on the label for its medication, Zoloft, that two studies had found the drug no better than sugar pills; however, the FDA insisted that

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[131] Vedantam, *supra* note 127, at A6. *See* Antidepressants Hearing, *supra* note 24.

[132] Vedantam, *supra* note 127, at A6. Almost two months later, however, the FDA did issue a "talk paper" to medical professionals concerning antidepressant use in the pediatric population, but it continued to maintain that it was "not yet clear whether antidepressants contributed to the emergence of suicidal thinking and behavior." FOOD & DRUG ADMIN., TALK PAPER, FDA ISSUES PUBLIC HEALTH ADVISORY ON CAUTIONS FOR USE OF ANTIDEPRESSANTS IN ADULTS AND CHILDREN (2004), *available at* http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01283.html. Additionally, a public health advisory published on the same date asserted that the "FDA has not concluded that these drugs cause worsening depression or suicidality." FOOD & DRUG ADMIN., PUBLIC HEALTH ADVISORY, WORSENING DEPRESSION AND SUICIDALITY IN PATIENTS BEING TREATED WITH ANTIDEPRESSANT (2004), *available at* http://www.fda.gov/cder/drug/antidepressants/AntidepressantPHA.htm.

[133] Okie, *supra* note 130, at 1063; Vedantam, *supra* note 127, at A6; Harris, *supra* note 122, at A1.

[134] Harris, *supra* note 122, at A1.

[135] Antidepressants Hearing, *supra* note 24; Shankar Vedantam, *FDA Urged Withholding Data on Antidepressants*, WASH. POST, Sept. 10, 2004, at A2.

[136] Vedantam, *supra* note 135, at A2.

existing language suggesting that efficacy had not been established for depressed children was sufficient.[137]

FDA officials apparently adopted this approach due to concerns that divulging such information might scare physicians and their patients' families away from the drugs.[138] Congressional committee members were incredulous with such reasoning, questioning why the FDA would not instead want to encourage such disclosures.[139] The agency's hesitancy to disseminate information would, however, continue to be the subject of congressional investigation and the source of public controversy.

B. Pain Relievers and Cardiovascular Risk

1. Merck's Vioxx

On September 30, 2004, Merck withdrew its pain medication Vioxx[140] from the market due to clinical trial data that demonstrated a significant risk of cardiovascular incidents such as heart attacks and strokes.[141] This represented the largest prescription-drug recall in history, as more than eighty million patients had formerly utilized this medication with annual sales for Merck estimated at more than $2.5 billion dollars.[142] In announcing this decision, Merck maintained that it had only recently learned of complications associated with the drug, but deemed such swift action appropriate as the company was committed to placing patient safety first.[143] However,

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[137] Antidepressants Hearing, *supra* note 24; Vedantam, *supra* note 135, at A2.

[138] Vedantam, *supra* note 135, at A2.

[139] *Id.*

[140] While Merck generally marketed the medication using the trade name Vioxx, the medication is also known as rofecoxib.

[141] News Release, MERCK, MERCK ANNOUNCES VOLUNTARY WORLDWIDE WITHDRAWAL OF VIOXX (Sept. 30, 2004), *available at* http://www.merck.com/newsroom/vioxx_withdrawal/pdf/vioxx_press_release_final.pdf (last visited Feb. 4, 2009).

[142] Eric J. Topol, *Failing the Public Health—Rofecoxib, Merck, and the FDA*, 351 NEW ENG. J. MED. 1707, 1707 (2004).

[143] MERCK, *supra* note 141; Anna Wilde Mathews and Barbara Martinez, *E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage*, WALL ST. J., Nov. 1, 2004, at A1.

internal company documents and interviews with outside scientists later revealed that Merck had in fact engaged in a deliberate campaign for years to conceal study results which demonstrated significant risks associated with the drug in order to prevent any negative impact on the sales of Vioxx.[144]

As early as the mid-1990's company officials became concerned that studies comparing less expensive pain relievers with Vioxx would reveal that its drug had much greater cardiovascular risks.[145] Therefore, executives at Merck discussed how to design a clinical trial that would potentially minimize the unfavorable comparison.[146] At the same time, however, they recognized that such concealment would be difficult.[147] In fact, one company e-mail warned that a proposed study may provide evidence that patients taking Vioxx had more blood clots than those clinical trial participants receiving standard treatment which could "kill [the] drug."[148] Eventually, however, Merck chose not to conduct a trial to exclusively research potential cardiovascular risks.[149] Instead, company officials decided to simply monitor trials that had been previously planned to test Vioxx for other possible uses to determine if any additional evidence of heart attacks, strokes, or related problems emerged.[150]

In May of 1999, Merck received FDA approval to distribute

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[144] Mathews & Martinez, *supra* note 143, at A1. *See* Alex Berenson et al., *DANGEROUS DATA – Retracing a Medical Trail: Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES, Nov. 14, 2004, § 1 at 1. Both the Wall Street Journal and the N.Y. Times were able to obtain access to copies of the confidential internal Merck documents.

[145] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[146] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[147] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[148] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[149] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[150] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

Vioxx for the treatment of arthritis, as well as to provide relief from other types of pain. In March of 2000, the results from a study entitled VIGOR[151] of more than 8,000 rheumatoid arthritis patients that compared Vioxx to the conventional pain reliever naproxen indicated a significant difference in the number of cardiovascular problems. The clinical trial participants that received Vioxx were five times as likely to have a heart attack as those in the naproxen group. Upon review of the data, the chief of research at Merck acknowledged in an internal company e-mail that cardiovascular risks "are clearly there" and the differences were so dramatic that it could not solely be explained by any sort of protective effect offered by naproxen.[152] Nonetheless, in a press release issued a month later, Merck downplayed the problems associated with Vioxx, stating that the VIGOR trial results were "consistent with" naproxen's clot-preventing properties.[153] The following month, the company announced in another press release that it had "confirm[ed the] favorable cardiovascular safety profile of Vioxx."[154] Although it referred to the results of the VIGOR study, it proclaimed that other trials had shown "NO DIFFERENCE in the incidence of cardiovascular events" between Vioxx and other pain relievers or placebos.[155]

In November of 2000, an article on the VIGOR trial results appeared in the *New England Journal of Medicine*.[156] The piece was written by Merck employees, as well as academics who had financial ties to the company.[157] It described the gastrointestinal benefits associated with Vioxx and the rates of heart attacks in the study. However, it implied that the

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[151] The name VIGOR was an acronym for Vioxx Gastrointestinal Outcomes Research.

[152] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[153] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[154] Mathews & Martinez, *supra* note 143, at A10.

[155] *Id.*

[156] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[157] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

increase in cardiovascular incidents only occurred in connection with patients already at high risk for heart attacks. Furthermore, the article failed to provide information concerning other cardiovascular complications, such as strokes or blood clots.[158]

In 2001, the first significant article critical of Vioxx was published in the Journal of the American Medical Association, raising public concern over the risks associated with the medication.[159] Nonetheless, Merck continued to publicly maintain that clinical trial data suggested naproxen's cardiovascular benefits were responsible for the differences in the rate of heart complications, not problems associated with the company's drug.[160] At approximately the same time, however, Merck prepared a marketing document directed to "all field personnel with responsibility for Vioxx" that provided an "obstacle handling guide."[161] If a sales representative encountered a doctor that was worried Vioxx could potentially raise the risk of a heart attack, the Merck employee was to respond by stating the drug "would not be expected to demonstrate reductions" in cardiovascular incidents and that it was "not a substitute for aspirin."[162] This evasiveness training also included a document aptly entitled "Dodge Ball Vioxx" which contained a listing of concerns doctors might be expected to bring up regarding the safety of the medication and then offered standard responses intended to neutralize the issue.[163]

In September 2004, preliminary data from another Merck

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[158] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[159] D.M. Mukherjee et al., *Risk of cardiovascular events associated with selective COX-2 inhibitors*, 286 JAMA 954 (2001). One of the authors of the article stated in an interview that Merck scientists visited him in an effort to convince him not to publish the piece. Merck officials have denied this allegation. *See* Berenson et al., *supra* note 144, § 1 at 1.

[160] Mathews & Martinez, *supra* note 143, at A10

[161] *Id.*

[162] *Id.*

[163] *Id.* at A1. Additionally, the final four pages of the document each contained a single word in capital letters: "DODGE!" Merck officials maintain that they instructed their employees to be honest and ethical. *Id.*

clinical trial labeled APPROVe,[164] which was designed to study whether Vioxx might be useful in preventing colon polyps, generated significant alarm.[165] Despite the fact that patients were not eligible to enroll in the trial if they had any evidence of cardiovascular disease, those participants that were treated with Vioxx had approximately twice as many heart attacks or strokes as compared to those receiving only a placebo.[166] Additionally, company officials were informed that a safety monitoring board wanted to immediately terminate the study because of the potential for harm to the research subjects.[167] As a result, Merck could no longer defend against the mounting public concern surrounding Vioxx and therefore had virtually no choice but to voluntarily remove the drug from the marketplace.[168]

2. An Inquiry into the FDA's Actions Concerning Vioxx

Not only was Merck under investigation for its handling of Vioxx, but the FDA's role in the controversy was also being carefully examined. Commentators increasingly claimed that the agency failed to observe the many warning signs that emerged, or even worse, intentionally suppressed critical information pertaining to the drug.[169] In November of 2004, a Senate committee held a hearing to explore whether the agency disregarded its responsibilities to protect the public from dangerous medications.[170] Evidence began to surface that questions concerning the cardiovascular safety had been raised

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[164] The name APPROVe was an acronym for Adenomatous Polyp Prevention of Vioxx.

[165] Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[166] Topol, *supra* note 142, at 1708. *See* Mathews & Martinez, *supra* note 143, at A1; Berenson et al., *supra* note 144, § 1 at 1.

[167] Mathews & Martinez, *supra* note 143, at A1.

[168] *Id.*

[169] *See, e.g.*, Topol, *supra* note 142, at 1707; Daniel H. Solomon et al., *Relationship Between Selective Cyclooxygenase-2 Inhibitors and Acute Myocardial Infarction in Older Adults*, 109 CIRCULATION 2068 (2004). *See also* Berenson et al., *supra* note 144, § 1 at 1 (discussing additional non-Merck sponsored studies that raised concerns about Vioxx).

[170] *FDA, Merck and Vioxx: Putting Patient Safety First: Hearing Before the S. Comm. on Finance*, 108th Cong. (2004) [hereinafter *Vioxx Hearing*].

by drug reviewers at the FDA even before Vioxx was approved.[171]

However, when Merck submitted the initial results from the VIGOR study to the agency in March of 2000, the FDA was quite alarmed by the findings.[172] While the company argued the significantly greater risk of cardiovascular events suffered by participants treated with Vioxx was due to the fact that they did not receive the cardioprotective properties of naproxen, the agency was quite skeptical.[173] Even top officials at the FDA testified that they found Merck's explanation unconvincing.[174] Nonetheless, nearly two years passed before the FDA required Merck to alter its drug label on Vioxx to include information regarding the cardiovascular risks. However, following negotiations with the company, the agency allowed such changes to be placed in the "Precautions" section following claims touting the gastrointestinal benefits of the drug, rather than prominently displaying it as a "Warning."[175]

In the meantime, Dr. David J. Graham, an epidemiologist who monitors drug safety for the agency, conducted an exceptionally large review of patients who had been treated with Vioxx to determine the incidence of cardiovascular problems potentially associated with its use.[176] The project took nearly three years to complete and confirmed that the drug was responsible for a substantial rise in cases of heart disease. Dr. Graham would eventually conclude, in his peer-reviewed article appearing in the prestigious medical journal *The Lancet*, the

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[171] *Id.*; Berenson et al., *supra* note 144, § 1 at 1.

[172] *Vioxx Hearing*, *supra* note 170; Berenson et al., *supra* note 144, § 1 at 1.

[173] *Vioxx Hearing*, *supra* note 170; Berenson et al., *supra* note 144, § 1 at 1.

[174] *Vioxx Hearing*, *supra* note 170. The deputy director of the FDA's Office of New Drugs stated with regard to Merck's explanation, "We just didn't buy that." *Id.*

[175] *Vioxx Hearing*, *supra* note 170; Anna Wilde Matthews, *Did FDA Staff Minimize Vioxx's Red Flags?*, WALL ST. J., Nov. 10, 2004, at 11. Interestingly, at the congressional hearing, Dr. David J. Graham testified the drug's label change was wholly inadequate as it "had absolutely no effect on how often high-dose Vioxx was prescribed." *Vioxx Hearing*, *supra* note 170. At this point in time, Graham believed the appropriate course of action based on the available evidence was to place the cardiovascular risk information in the "Warnings" section, as well as implement a complete ban on a high-dose formulation of the drug. *Id.*

[176] *Vioxx Hearing*, *supra* note 170.

increased risk attributable to Vioxx was 3.7 times.[177] This translated into approximately 100,000 excess cases of heart disease, with almost half of these being fatal.[178]

However, these findings almost never became public. After Dr. Graham first approached his superiors in early August of 2004 with the results of the study, he was subsequently pressured to change his conclusions by senior officials at the FDA.[179] He was told that as the agency was not contemplating a warning against the use of high-dose Vioxx, his contradictory recommendations were not acceptable.[180] Additionally, Dr. Graham was informed that if he failed to make the necessary modifications, he would not be permitted to present the data at an upcoming conference at which he was scheduled to speak.[181] Moreover, Dr. Graham was notified by a manager in the Office of Drug Safety that he would need to provide his original study results to Merck.[182]

Eventually, Dr. Graham reluctantly conceded to his supervisors' demands by altering the results quite considerably in advance of the conference.[183] Dr. Graham testified at the Senate hearing that he did so "because [he] thought if [he] did not, there would be no way on earth that [the] data would see the light of day."[184] The FDA's apparent disregard for safety concerns and resistance to disclosure would further strengthen the growing public sentiment that greater transparency was urgently needed in connection with clinical trials.

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[177] D. Graham et al., *Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients treated with Cyclo-oxygenase 2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs*, 365 LANCET 475, 479 (2005).

[178] *Id.* at 480. *See also* Vioxx Hearing, *supra* note 170.

[179] *Vioxx Hearing*, *supra* note 170.

[180] *Id.*

[181] *Id.*

[182] *Id.*

[183] *Id.*

[184] *Id.*

IV. INCREMENTAL MOVEMENT TOWARD GREATER ACCESS TO CLINICAL TRIAL INFORMATION

Scientists and patient advocates have long reported substantial difficulties associated with obtaining data concerning clinical trials. For more than thirty years, the creation of a clinical trial registry which could provide basic information regarding ongoing trials had been proposed as a partial solution to the problem.[185] While the National Institutes of Health ("NIH") registered all of the studies it sponsored from 1975 to 1979, the agency discontinued this policy until the Food and Drug Act was amended almost two decades later.

The Food and Drug Administration Modernization Act of 1997 ("FDAMA") mandated the creation of a registry that would provide data on clinical trials for serious or life-threatening diseases.[186] The statute required the information to be "in a form readily understood by members of the public" and include a description of the study's purpose, eligibility criteria for participation, trial phase, location of study sites, and the drug or therapy under investigation.[187] Additionally, registration was mandatory regardless of whether the trial was publicly or privately funded.[188]

In fulfillment of the statutory obligations under the FDAMA, the FDA and NIH created the ClinicalTrials.gov website. This register, maintained by the United States National Library of Medicine, became operational in early 2000.[189] Nonetheless, the pharmaceutical industry was

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[185] Kay Dickersin & Drummond Rennie, *Registering Clinical Trials*, 290 JAMA 516, 516 (2003).

[186] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997). The Act limited the registration requirement to clinical trials testing the effectiveness of experimental drugs or biological products, as opposed to trials merely studying toxicity. *Id.* Essentially, this would include all Phase 2, Phase 3, and Phase 4 trials that contain efficacy endpoints as part of their study protocol. *Id.*

[187] *Id.*

[188] *Id.*

[189] FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES AND CONDITIONS 2 (2004), *available at* http://www.fda.gov/cber/gdlns/clintrial031802.pdf.

exceptionally resistant to providing the required disclosures.[190] In clear contravention of the FDAMA's provisions, the pharmaceutical industry stated that it would not pledge to register its clinical trials. In a document entitled "Public Disclosure of Clinical Trial Results," the drug companies' trade group declared that "[s]ponsors do not commit . . . to make the designs of clinical trial protocols available publicly at inception, as in a clinical trials registry."[191]

Accordingly, the pharmaceutical industry repeatedly failed to comply with the law. For example, a study by FDA staff found that less than half of all cancer trials sponsored by drug companies required to be registered were actually submitted to clinicaltrials.gov, in comparison to more than ninety percent of government-funded trials.[192] Another review of ongoing prostate and colon cancer clinical trials demonstrated similar deficiencies, as only seventeen of the thirty-two trials sponsored by industry were registered.[193] For other serious diseases the study inclusion rate was even more abysmal, with some in the mere single digits.[194] Furthermore, when drug companies actually did tender information to the clinicaltrials.gov registry, the information provided was often inadequate.[195] Including meaningless information, such as "investigational drug" in place of the actual name of the medication as required by the statute or omitting the sponsor's name, was commonplace.[196]

Such a state of affairs was due in large part to the fact that there were no negative consequences associated with a trial

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[190] Dickersin & Rennie, *supra* note 185, at 516.

[191] PHARM. RESEARCH & MFRS. OF AM., PRINCIPLES ON CONDUCT OF CLINICAL TRIALS AND COMMUNICATION OF CLINICAL TRIAL RESULTS (2002).

[192] J. Derbis, et al., *FDAMA Section 113: Information Program on Clinical Trials for Serious and Life-Threatening Diseases,* Ninth Annual Food and Drug Administration Science Forum (2003), abstract *available at* http://www.cfsan.fda.gov/~frf/forum03/U-04.htm (last visited Feb. 4, 2009).

[193] Dickersin & Rennie, *supra* note 185, at 519.

[194] Vedantam, *supra* note 14, at A1.

[195] Catherine DeAngelis et al., Is This Clinical Trial Fully Registered?—A Statement from the International Committee of Medical Journal Editors, 352 NEW ENG. J. MED. 2436, 2436-38 (2005); Deborah Zarin et al., Issues in the Registration of Clinical Trials, 297 JAMA 2112, 2115-18 (2007).

[196] Zarin et al., *supra* note 195, at 2115.

sponsor's violation of the FDAMA. The FDA did not require companies to register their clinical studies in order to utilize the data from the investigations for regulatory approval.[197] Furthermore, refusal to submit information to the publicly accessible ClinicalTrials.gov registry did not lead to any sort of a monetary penalty.

With the anti-depressant and Vioxx controversies as a backdrop, there were increasing demands placed on Congress to considerably improve the level of transparency in the drug approval process and provide greater public access to clinical trial information. Consequently, in October of 2004, members in both houses of Congress introduced their own versions of the Fair Access to Clinical Trials (FACT) Act, which attempted to ameliorate many of the inadequacies associated with the FDAMA's clinical trial registry provisions.[198] Although the bills were not identical, they were quite similar, including requiring registration of a study as a prerequisite to FDA authorization for testing an investigational medication.[199] Additionally, the Department of Health and Human Services would have the authority to impose civil penalties of $10,000 per day for noncompliance.[200] Even more significant, both of the bills would expand the type of information a drug company would need to disclose, most notably through the creation of a new clinical trial results database that would contain a modest amount of factual material from completed studies.[201]

Not surprisingly, the pharmaceutical industry's trade group

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[197] This was in stark contrast to an investigator's failure to obtain prior IRB approval of research protocols, which could result in an inability to submit the findings from such trials to the FDA. *See* 21 C.F.R. §54.1(b) (2008) and the discussion of the IND process in Section III *supra.*

[198] Fair Access to Clinical Trials Act, H.R. 5252, 108th Cong. (2004); Fair Access to Clinical Trials Act, S. 2933, 108th Cong. (2004).

[199] Fair Access to Clinical Trials Act, H.R. 5252; Fair Access to Clincial Trials Act, S. 2933. *See* Robert Steinbrook, *Registration of Clinical Trials—Voluntary or Mandatory?*, 351 NEW ENG. J. MED. 1820 (2004) (providing a detailed analysis of the type of information to be included under the Fair Access to Clinical Trials Act).

[200] Fair Access to Clinical Trials Act, H.R. 5252; Fair Access to Clinical Trials Act, S. 2933.

[201] Fair Access to Clinical Trials Act, H.R. 5252; Fair Access to Clinical Trials Act, S. 2933.

did not support the FACT Act. Originally, the Pharmaceutical Research and Manufacturers of America (PhRMA) asserted that a results reporting requirement was unnecessary.[202] However, in January of 2005, faced with pressure from lawmakers, the medical community, and the public, the four largest pharmaceutical trade groups in the world, including PhRMA, released a joint statement on the disclosure of clinical trial information.[203] While the group members pledged to release a nominal amount of information regarding ongoing trials, they did not commit to submitting the data to a comprehensive, government-sponsored registry.[204] Instead, the provisions left open the possibility of publishing the information on individual, company-sponsored websites that could contain internal rules that might not be publicly disclosed and consequently may differ from one site to the next. A 2006 study confirmed that the potential for abuse of such a system was far from theoretical, finding that "when conclusions were listed in these [corporate] databases, they tended to be more favorable for the company's product than those found in published articles or FDA reviews of the same trials."[205] Furthermore, with regard to completed trials, the pharmaceutical manufacturers agreed only to make public "summary results" of the studies and, additionally, asserted such disclosure "must maintain protections for . . . intellectual property and contract rights."[206] Most problematic, however, was the fact that adherence to the proposed guidelines was completely voluntary.

Ultimately, neither version of the FACT Act of 2004 was

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[202] *See, e.g.*, Barry Meier, *Contracts Keep Drug Research Out of Reach*, N.Y. TIMES, Nov. 29, 2004, at A1 (reporting on the pharmaceutical industry's response to the proposed legislation).

[203] INT'L FED'N OF PHARM. MFR. & ASS'N, GLOBAL INDUSTRY POSITION ON DISCLOSURE OF INFORMATION ABOUT CLINICAL TRIALS (2005), *available at* http://clinicaltrials.ifpma.org/fileadmin/files/pdfs/EN/CTP_Release_Joint_Position_EN.pdf. The statement included trade groups from the United States, Japan, as well as Europe. *Id.*

[204] *Id.*

[205] Zarin et al., *supra* note 195, at 2118.

[206] INT'L FED'N OF PHARM. MFR. & ASS'N, JOINT POSITION ON THE DISCLOSURE OF CLINICAL TRIAL INFORMATION VIA CLINICAL TRIAL REGISTRIES AND DATABASES (2005), *available at* http://en.sanofi-aventis.com/binaries/050106_release_en_tcm28-21769.pdf.

enacted as both bills did not succeed in making it out of committee. Over the next few years, a number of comparable bills were introduced in the House and Senate,[207] as well as a few alternative proposals;[208] nevertheless they all met a similar fate. However, in 2007, with a substantial FDA funding program[209] set to expire that had dramatically reduced the review time of drug applications to the major benefit of the pharmaceutical companies, consumer groups and the medical community began to advocate for other provisions to be added to the reauthorization bill in order to improve drug safety. As a result, the push for the creation of a clinical trial results database increasingly gained momentum, and it soon became clear that the pharmaceutical industry would likely need to concede to at least some level of disclosure.

On May 9, 2007, the Senate passed the Food and Drug Administration Revitalization Act,[210] containing clinical trial results database provisions adopted from a bill introduced earlier in the year, the Enhancing Drug Safety and Innovation Act of 2007.[211] On June 28, 2007, the House of Representatives passed its own reauthorization bill, the Food and Drug Administration Amendments Act of 2007.[212] The portion of the legislation pertaining to study results, although far from ideal, did contain some significant improvements over the Senate's version that certainly strengthened the bill. Unfortunately, under pressure from the pharmaceutical lobby, the final compromise legislation approved by both houses of Congress and eventually enacted into law removed most of these enhancements. Ultimately, the clinical trial results database provisions failed to impart the critical transparency necessary to

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[207] Fair Access to Clinical Trials Act, H.R. 3196, 109th Cong. (2005); Fair Access to Clinical Trials Act, S. 470, 109th Cong. (2005); Fair Access to Clinical Trials Act, S. 467, 111th Cong. (2007).

[208] *See, e.g.*, Enhancing Drug Safety and Innovation Act, S. 3807, 110th Cong. (2006); Enhancing Drug Safety and Innovation Act, S. 3807, 111th Cong. (2007).

[209] *See infra* Part VIII discussing the arguably problematic conflict of interest created by this program.

[210] Food and Drug Administration Revitalization Act, S. 1082, 111th Cong. (2007).

[211] Enhancing Drug Safety and Innovation Act, S. 484, 111th Cong. (2007).

[212] Food and Drug Administration Amendments Act, H.R. 2900, 111th Cong. (2007).

provide meaningful reform to the clinical trial process and thus adequately protect the public.

V. DEFICIENCIES OF THE FEDERAL CLINICAL TRIALS RESULTS DATABASE REQUIREMENTS

On September 27, 2007, the Food and Drug Administration Amendments Act (FDAAA) became law.[213] With regard to the clinical trials registry portion of the Act, the statute did achieve some limited success. A number of the major shortcomings associated with the Food and Drug Administration Modernization Act's ("FDAMA") clinical trial registry were remedied. Of particular significance was the fact that monetary penalties could now be assessed for the failure to register an applicable clinical trial.[214] Additionally, the provisions were changed so that clinical trials related to all conditions, not merely those studies pertaining to serious or life-threatening diseases, now had to be registered.[215] Nonetheless, several anticipated modifications were not instituted.[216]

The FDAAA also required the Secretary of Health and

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[213] Food and Drug Administration Amendments Act of 2007, Pub. Law No. 110-85, 121 Stat. 823 (codified as amended at 21 USC §§ 301 *et seq.*).

[214] *See* Section IV *supra* discussing the inadequacies of the FDAMA's clinical trial registry provisions. The statute now provides for monetary penalties in the amount of $10,000 for all violations adjudicated in a single proceed. 21 U.S.C. §333 (2006 & Supp. 2008). However, to the extent a violation is not corrected within the thirty-day period following notification of non-compliance, an additional fine of $10,000 per day may be assessed until such problem is corrected. *Id.*

[215] 42 U.S.C. § 282(j)(1)(A)(iii)(I) (2006 & Supp. 2008) (defining an "applicable drug clinical trial").

[216] One important change not made was an amendment to require that all submissions of registration information conform to the International Clinical Trials Registry Platform trial registration data set of the World Health Organization developed in 2004. This worldwide uniform standard contains a twenty-item minimum data set. *See* WORLD HEALTH ORG., INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM, *available at* http://www.who.int/ictrp/en/. Ironically, compliance with the standard was originally included in both of the bills passed in the House and Senate, but was removed as part of the compromise legislation eventually enacted into law, omitting several of the mandatory categories of information. Additionally, another modification that would have appreciably strengthened the clinical trials registry would be to require Phase I trials to be listed. *See infra* Part VII further examining the importance of incorporating these early trials.

Human Services ("Secretary") to expand the clinicaltrials.gov registry to include results of clinical trials for the first time.[217] While this portion of the Act was generally heralded by Congress as a major triumph for public safety,[218] in reality it appears to be more of a victory for the pharmaceutical industry. A closer look at the statutory language demonstrates the legislation as currently configured requires minimal disclosure and continues to allow drug companies to maintain a shroud of secrecy surrounding the vast majority of clinical trial result information.

A. The First Stage of Controlled Disclosure

The statute is essentially configured to disclose particular categories of information in successive stages. The initial stage requires that not later than ninety days after the enactment of the FDAAA, the Secretary must ensure links have been created from the ClinicalTrials.gov registry to a very narrow grouping of result information.[219] This includes any public health advisories issued by the FDA regarding the drug that is the subject of the clinical trial and any previously published FDA summary documents resulting from an advisory committee meeting that considered the research study.[220] Additionally, this requirement generally only pertains to Phase III or the typically voluntary post-approval studies conducted by drug manufactures in consultation with the FDA, also known as Phase IV clinical trials.[221] Furthermore, such links need not be established any earlier than thirty days after the date the drug is approved or prior to thirty days after the specified data has become publicly available by other means.[222] The ultimate effect of these exceptionally restrictive provisions is to merely provide an additional website location to access this extraordinarily limited

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[217] 42 U.S.C. § 282(j)(3) (2006 & Supp. 2008).

[218] *See* Section I *supra* discussing the inaccurate portrayal of the Act by its sponsors.

[219] § 282(j)(3).

[220] § 282(j)(3)(A)(ii).

[221] § 282(j)(3)(A)(iii) ("those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved").

[222] § 282(j)(3)(A)(i).

amount of previously obtainable information.[223] While this might theoretically allow individuals to retrieve the relevant material more easily, it certainly does not obligate the drug industry to divulge any unattainable results information.

B. The Second Stage of Controlled Disclosure

The second stage of data disclosure is set to occur no later than one year after the enactment of the statute.[224] By this time frame, the Secretary must further expand the clinical trial results database to contain additional information. Material to be incorporated includes rudimentary demographic baseline characteristics of the patients participating in the study.[225] This must also include the number of individuals who dropped out of the clinical trial.[226] Disappointingly, no information need be provided as to the reason for withdrawing, which could furnish potentially valuable insight as to possible problems associated with the intervention.

Further, very basic data concerning the primary and secondary outcome measures must also be submitted.[227] Moreover, the existence of an agreement which restricts the ability of the principal investigator ("PI") to publicly discuss the results of the trial after its completion needs to be divulged.[228] Unfortunately, this obligation is narrowed significantly by its failure to include persons other than the PI. Drug companies frequently utilize medical schools with their academic scientists and teaching hospital personnel to run clinical trials[229] which would not be included in this disclosure. Moreover, this requirement is inapplicable if the PI is also an employee of the

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[223] Virtually all of this information would have previously been made available on the FDA or National Institutes of Health's own publicly accessible Internet website.

[224] § 282(j)(3)(C).

[225] § 282(j)(3)(C)(i).

[226] *Id.*

[227] § 282(j)(3)(C)(ii). Outcome measures in a clinical trial involving a new drug for the treatment of early-stage breast cancer might for example include the number of participants who were diagnosed with a recurrence of their breast cancer as a primary outcome and then the number of patients who ultimately died as a secondary outcome.

[228] § 282(j)(3)(C)(iv)(2008).

[229] Meier, *supra* note 202, at A1.

sponsor. As it is not unusual for industry-sponsored trials to designate one of their in-house scientific researchers to be the PI, this requirement is far from adequate.[230]

Even more problematic, however, is the fact these already limited disclosures do not pertain to those later studies involving drugs that ultimately fail to receive FDA approval.[231] This is exceptionally troubling as failure to integrate clinical trial results data from studies on a drug that is ultimately not approved will severely impact the quantity of information made available to the general public. Even by the pharmaceutical industry's own estimates, only twenty percent of investigational medications successfully complete all three phases of the clinical testing process and consequently become the subject of a New Drug Application.[232] Moreover, not all of these pharmaceuticals will actually obtain FDA approval.[233] As a result, the overall number of trials potentially subject to this second round of possible disclosures is exceedingly small.

Additionally, the statutory provisions further narrow this already extremely limited group of clinical trials by also providing that results from Phase I trials need not be submitted.[234] This is quite disconcerting as releasing such details is essential to ensuring future patient safety. This is well illustrated by the case involving TGN1412, a monoclonal antibody developed by drug manufacturer TeGenero that was

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[230] It should also be pointed out that this provision would not provide any sort of assistance to individuals such as Dr. Mosholder and Dr. Graham as they are employees of the FDA. Furthermore, this disclosure requirement is only with regard to "applicable clinical trials," which as defined by the Act applies solely to prospective clinical trials, not the sort of retroactive review studies conducted by Dr. Mosholder and Dr. Graham of anti-depressants and Vioxx respectively. Interestingly, the FDAAA also contained a section concerning policies on the review and clearance of scientific articles by FDA employees, which continues to allow for the agency to potentially exercise significant control. *See* 21 U.S.C § 379 (2006 & Supp. 2008).

[231] 42 U.S.C. § 282(j)(3)(C) (2006 & Supp. 2008).

[232] U.S. GOV. ACCOUNTABILITY OFFICE, *supra* note 42, at 7.

[233] *Id.* (explaining that the percentage of applications that are ultimately denied approval is approximately twenty-five percent)

[234] 42 U.S.C. § 282(j)(1)(A)(iii)(I) (2006 & Supp. 2008) (defining applicable drug clinical as a "controlled clinical investigation, other than a phase I clinical investigation of a drug subject to section 355 of Title 21 or to section 262 of this title.").

thought could potentially benefit individuals suffering from multiple sclerosis or rheumatoid arthritis.[235] Six healthy volunteers enrolled in the study were to be the first humans to receive the treatment. However, within a few hours after administration of the drug, all of the participants began experiencing multiple-organ failure and were quickly transferred to an intensive care unit. Although every individual survived the incident, some of the study volunteers remained hospitalized for up to three months. By failing to include results data from all trial phases, it is quite possible another pharmaceutical company might unknowingly repeat previous mistakes in studies of the same or similar medication, thereby needlessly placing patients at significant risk for substantial harm.

The overall impact of these restrictions is the number of clinical trials subject to these disclosure requirements is exceedingly small. Consequently, this has a dramatic impact on the amount of information that pharmaceutical companies need make publicly accessible. As such, this statutory section does not lead to anything approaching meaningful change in terms of the depth or breadth of significant clinical trial results data that must be revealed

C. The Third Stage of Controlled Disclosure

The third and final stage of expansion of the results database is exceptionally unsettled. The only information that must definitively be revealed are the elements included in the prior stage.[236] This is due to the fact that instead of specifying any additional disclosure obligations, the Act directs the Secretary to expand the results database through regulation not later than three years from the enactment date of the Act.[237] In connection therewith, the statute requires that a public meeting

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[235] *See, e.g.*, Alistair J.J. Wood & Janet Darbyshire, *Injury to Research Volunteers—The Clinical-Research Nightmare*, 354 NEW ENG. J. MED. 1869 (2006).

[236] 42 U.S.C. § 282(j)(3)(D)(iii) (2006 & Supp. 2008) ("The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C) . . . .)

[237] § 282(j)(3)(D)(i).

be held no later than eighteen months after the date of enactment "to provide an opportunity for input from interested parties."[238] As such, this would undoubtedly seem to allow for significant input from drug companies in shaping the clinical trial results information to be divulged under this provision of the FDAAA. In fact, an earlier Senate version of the Act made participation in further negotiated rule making explicit, requiring the formation of a committee that mandated the inclusion of members representing the pharmaceutical industry.[239]

The Act stipulates that the final regulations promulgated must include a summary of the clinical trial and its results written in non-technical language that is understandable to the general public, as well as an additional scientific summary appropriate for researchers and medical professionals.[240] Nevertheless, such disclosures are only necessary if the Secretary determines these summaries can be communicated in a manner that is not misleading or promotional in nature.[241] Concerns have been raised that such narratives might provide an opportunity for those entities with vested interests in the manner in which the results are depicted to provide a biased spin on the way the data is portrayed.[242] Consequently, the Act provides that, if the Secretary ultimately concludes this is not possible, the disclosures will not be required.[243] However, an argument can be made that these lay summaries are essential to ensuring patients have access to understandable information regarding clinical trials, as well as provide a form of acknowledgement to the risks study volunteers take by participating in the research studies.[244] As a result, the solution

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[238] § 282(j)(3)(D)(vii).

[239] Food and Drug Administration Revitalization Act, S. 1082, 111th Cong. (2007).

[240] § 282 (j)(3)(D)(iii)(I-II).

[241] *Id.*

[242] *See e.g.* Zarin et al., *supra* note 195, at 2115-18.

[243] § 282(j)(3)(D)(iii)(I-II).

[244] Aneel Damle et al., *A Policy Study of Clinical Trial Registries and Results Databases* (2007), *available at* http://www.citizen.org/publications/release.cfm?ID=7534&secID=1656&catID=126.

is not to prohibit the summaries altogether, but ensure the ability to access the raw data to audit the information contained within the narrative, as well as provide a mechanism to make any necessary changes.

Similarly, an additional provision initially appears to compel the creation of a regulation calling for the submission of the entire clinical trial protocol for public review.[245] However, this obligation is further weakened since an option exists to limit this solely to such protocol information necessary "to help to evaluate the results of the trial."[246] As a result, it is quite possible that very little information will actually be disseminated.

To the extent the regulations introduced by the Secretary provide for further disclosure of clinical trial results, such new rules only pertain to specific studies. Similar to previous sections, Phase I studies are not included.[247] Moreover, although the Act requires that results information from all investigations involving an FDA-approved medication be listed on the expanded ClinicalTrials.gov website, data from studies concerning pharmaceuticals that do not ultimately receive FDA-approval, regardless of whether authorization was sought, may not necessarily need to be publicly divulged.[248] This is due to the fact that instead of requiring these trials to be included at the outset, the Act instead provides the Secretary with the discretion to later determine whether or not to incorporate such studies into the publicly accessible database.[249] Again, as discussed above, since the vast majority of drugs fail to obtain FDA-approval, excluding all clinical trials of unapproved medications will provide pharmaceutical companies with the ability to continue concealing enormous amounts of information from the public.

Furthermore, the timeline for the actual dissemination of these trial results to the public is potentially quite lengthy.

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[245] § 282(j)(3)(D)(iii)(III).

[246] *Id.*

[247] § 282(j)(1)(A)(iii)(I).

[248] § 282(j)(3)(D)(ii)(I-II).

[249] § 282(j)(3)(D)(ii)(II).

Although the Act initially provides that submission of clinical trial data must occur no later than one year after the earlier of the estimated or actual completion date of the trial, there are some significant exceptions.[250] The statute allows data submissions to be delayed for a trial involving a previously approved drug that is undergoing testing for new, additional uses not currently part of the medication's labeling.[251] This would include, for example, the various clinical studies investigating the use of the antidepressant Paxil in pediatric populations or Merck's APPROVe trial examining whether Vioxx was effective in preventing colon polyps. As long as the pharmaceutical manufacturer intends to file an application seeking approval for the new use within one year and tenders the requisite certification attesting to such plans, the information need not be submitted until thirty days following the earlier of FDA approval of the new use, agency denial of the application, or the withdrawal of the application if not resubmitted within 210 days.[252] However, if one of these three actions has not occurred prior to two years from the date the extension was requested, the data must immediately be submitted.[253] The ultimate effect of the interaction between these various subsections of the Act is that data required to be disclosed regarding these clinical trials investigating off-label uses most likely will not become publicly available for approximately three years after the study is completed.[254] Clearly, the past controversies have illustrated that allowing clinical trial results data on off-label uses to be suppressed for

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[250] § 282(j)(3)(E)(i). It should be noted that this stipulated time frame could potentially be extended slightly as the Secretary has the power under the Act to increase the period for submission to eighteen months by regulation. *See* § 282(j)(3)(D)(iv)(I).

[251] § 282(j)(3)(E)(v).

[252] *Id.*

[253] 42 U.S.C. § 282(j)(3)(E)(v)(III) (2006 & Supp. 2008).

[254] This figure is calculated by adding the one-year time frame for the typical submission time, plus the approximate length of time it would take to obtain drug approval, denial of an application, or the two-year limitation period from when the certification is filed. So long as said certification is filed less than a year from the completion date of the study in question (or the expected completion date), the applicant would not appear to be out of compliance.

such a protracted period of time is completely unacceptable, as it continues to facilitate a system that does not adequately protect public safety.

Delays in submission of study results are also allowed for another category of trials, namely clinical investigations completed before the drug is initially approved.[255] With regard to such pre-approval studies, the statute allows the deadline to be extended until thirty days following the drug's approval date.[256] In light of the fact that all three phases of the clinical trial process generally take seven years to complete and the agency's application review process can typically be expected to last almost two years,[257] the duration of postponement permitted for release of the data, particularly from some of the earlier applicable trials, is nothing short of astonishing.

D. Further Weaknesses of the Act

Aside from the numerous special exceptions already articulated, the FDAAA also allows the Director of the National Institutes of Health to grant extensions to the second and third stage data submission requirements.[258] The only restriction on the Director's ability to provide relief from these disclosure obligations is that a request must demonstrate "good cause;" however, this term is not defined.[259] Additionally, the provision does not contain any sort of limitation on the permissible length of such an extension. Moreover, the Director is allowed to grant more than one extension for a particular clinical trial.[260] While some flexibility may be desirable, such an unnecessarily broad provision leaves open the potential for abuse.

Another serious shortcoming of the Act is its failure to specify at the outset the adverse event reporting requirements. Instead, this subject is left to be addressed through future

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[255] § 282(j)(3)(E)(iv).

[256] *Id.*

[257] U.S. GOV. ACCOUNTABILITY OFFICE, *supra* note 42, at 7.

[258] § 282(j)(3)(E)(vi).

[259] *Id.*

[260] *Id.*

regulation by the Secretary.[261] In the event the Secretary fails to issue such regulations within twenty-four months of the FDAAA's enactment, the statute does provide a series of default provisions, which will then go into effect.[262] However, considering the import of this type of information to other investigators who may be conducting clinical trials utilizing identical or similar interventions, physicians responsible for appropriately advising their patients, and the safety of the general public, these provisions should not have been left for future elaboration.

Similarly, the Act fails to stipulate a method for verifying the accuracy of the information that is submitted by study sponsors in accordance with the statute's various disclosure provisions.[263] As this is left to future regulation by the Secretary,[264] it is unclear how rigorous a process this ultimately may be in the end. However, procedures allowing for careful analysis of data provided in accordance with the Act are critical to ensuring necessary transparency.

Additionally, while not necessarily constituting a shortcoming of the FDAAA per se, it is worth noting that the Act also preempted all state provisions relating to the registration of clinical trials or the disclosure of study results in a database.[265] While over the last several years many states have introduced legislation concerning clinical trials, only Maine has succeeded in passing such a law.[266] The Maine state statute required that pharmaceutical companies make publicly accessible "[i]nformation concerning the results of the clinical trial, including potential or actual adverse effects of the drug" for all studies involving medications distributed in Maine.[267] While the exact contours of this provision would seem to have necessitated further rulemaking by the Maine Department of Health and

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[261] § 282(j)(3)(I).

[262] *Id.*

[263] § 282(j)(3)(D)(v)(III).

[264] *Id.*

[265] § 282(j).

[266] ME. REV. STAT. ANN. tit. 22, § 2700-A (2007).

[267] § 2700-A(3).

Human Services as afforded under the statute,[268] it is quite possible that the Maine state law could have potentially required significantly greater disclosure than the federal statute. However, as a result of the preemption provision, the possibility of correcting the deficiencies of the federal law indirectly through state legislation is foreclosed. Consequently, further strengthening of the FDAAA disclosure requirements must therefore now come in the form of regulations issued by the Secretary or amendments to the statute by Congress. Nevertheless, any attempt to expand the type or amount of results information to be publicly revealed will unquestionably meet strong resistance from the pharmaceutical industry.

VI. OPPOSITION TO DISCLOSURE

Pharmaceutical companies have been exceptionally resistant to mandatory requirements to publicly reveal clinical trial materials, particularly results data. The drug industry has typically taken the position that if they are paying for an investigational study, the data generated unquestionably belongs to them.[269] Moreover, as the purported owners of the information, they should be entitled to control its disclosure. This stance is further reflected in PhRMA's position paper entitled *Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results*, which succinctly provides: "As owners of the study database, sponsors have discretion to determine who will have access."[270]

The pharmaceutical industry has asserted a wide range of proprietary-based rationales for such viewpoints. Often this includes arguments sounding in trade secret, contract, and patent law. Additionally, drug manufacturers maintain that the

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[268] § 2700-A(7).

[269] *See e.g.*, Meier, *supra* note 202, at A1.

[270] PHARM. RESEARCH & MFRS. OF AM., PRINCIPLES ON CONDUCT OF CLINICAL TRIALS AND COMMUNICATION OF CLINICAL TRIAL RESULTS 21 (2004) [hereinafter PHRMA PRINCIPLES]. The document also declares that "[e]ven the fact that an exploratory study is being conducted may be highly proprietary because it reflects a company's choices to pursue certain research strategies, to test various methods of clinical trial design, and/or to utilize certain endpoint measures." *Id.*

ability to control clinical trial data is a competitive necessity, without which innovation would likely decrease to society's detriment. Furthermore, as much of the information is technical in nature, drug companies contend that releasing trial results to the general public is not only unlikely to be helpful, but could in fact lead to significant patient confusion or unwarranted concern. However, a closer look at these positions demonstrates their many weaknesses.

A. Trade Secrets

When the public began demanding further details concerning clinical trials involving the use of antidepressants in the pediatric population, the pharmaceutical makers refused.[271] Instead, they claimed the study results could not be released because they constituted trade secrets.[272] The FDA has also generally supported this line of reasoning.[273] The agency's longstanding policy is to treat information generated in connection with clinical trials as trade secrets.[274] Nonetheless, the FDA has indicated its hesitation about doing so.

The agency has testified on numerous occasions before Congress that federal law as currently drafted prohibits the dissemination of "useful information contained in the agency's files, and particularly, data relating to the safety and effectiveness of drugs."[275] Furthermore, the FDA has asserted that "[e]ven if such disclosure would be in the public interest, in order to protect the public health, and even if the Commissioner wishes as a matter of discretion to release such material, such disclosure cannot lawfully be undertaken."[276] Consequently, the agency is "bound by the present provisions until Congress acts."[277]

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[271] Shankar Vedantam, *Antidepressant Makers Withhold Data on Children*, WASH. POST, Jan. 29, 2004, at A1.

[272] *Id.*

[273] Availability of Records and Information, 42 Fed. Reg. 3,094 (Jan. 14, 1977).

[274] *Id.*

[275] Freedom of Information Act, 39 Fed. Reg. 44,602; 44,612 (Dec. 24, 1974).

[276] *Id.*

[277] *Id.*

However, it is not entirely clear that the statutory language invoked in support of this position actually provides for the claimed interpretation.[278] Trade secrecy proponents have generally relied on § 301(j) of the FDCA which prohibits the use of any information acquired in connection with the FDA approval process "concerning any method or process which as a trade secret is entitled to protection."[279] But a compelling argument can be made that clinical trial data does not actually constitute a "method or process."[280] Nonetheless, it may be unfeasible to adopt a more narrow interpretation of the statutory language at this stage in light of the FDA's established practice.[281]

Yet characterizing clinical trial data as a trade secret may be analytically difficult for still another reason. A fundamental tenet of trade secret law is that protection exists only as long as the information is kept confidential. The very nature of a clinical trial is quite public in many respects, making maintenance of complete secrecy fairly difficult.[282] Large numbers of human subjects are often involved and generally not restricted in their ability to communicate about their experiences, including adverse events. As a result, information that might be initially characterized as potentially sensitive is often readily obtainable. For example "detailed pipeline information on interventions and research from the preclinical phase to the market phase is already available through various subscription websites."[283] Furthermore, data on most late-phase drug trials is effectively in the public domain at the present time through academic presentations at scientific meetings.[284]

Disclosure of clinical trial data often also occurs in rather

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[278] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 380 (2007).

[279] *Id.*(citing Federal Food, Drug, and Cosmetic Act § 301, 21 U.S.C. § 331 (2000)).

[280] *Id.*

[281] *Id.*

[282] *A Prescription for Better Drug Trials*, 41 TRIAL 54, 55 (2005).

[283] Karmela et al, *supra* note 20, at 956; *see also* Ida Sim et al., *Clinical Trial Registration: Transparency is the Watchword*, 367 LANCET 1631, 1631 (2006).

[284] Gerd Antes and Iain Chalmers, *Under-reporting of Clinical Trials is Unethical*, 361 LANCET 978 (2003)

unexpected ways. For example, numerous reports have surfaced that preferred customers of Wall Street brokerage houses and hedge funds are frequently given access to clinical trial data, which is then used to make investment decisions.[285] While such practices were investigated by the Securities and Exchange Commission as potentially violating insider trading laws, the actions would also potentially extinguish any purported trade secret protection.[286] The conclusion that ultimately can be drawn is the drug industry's supposedly fail-safe argument regarding clinical trial data constituting trade secrets, is overall quite specious.

B. Contracts

Drug companies frequently rely on contracts in order to assert rights to the information collected in a clinical trial, as well as exercise virtually complete control over any communications related to the study data. It is not unusual for pharmaceutical makers to include in agreements with research scientists, and medical school personnel conducting the investigations on their behalf, a requirement that all data be maintained confidentially. Furthermore, these restrictions also usually include prohibitions on a researcher's ability to discuss the results of the trial publicly or even privately, as well as publish articles related to the study results.

While some academic institutions have opposed such constraints, for example Yale University will not accept any restrictions on publication with the exception of a short postponement to allow for a patent application or license, these entities are clearly in the minority.[287] In fact, the authors of a survey examining agreements between medical schools and industry sponsors found that "academic institutions rarely

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[285] *SEC Investigating Reports of Leaks of Clinical Trial Data*, 24 BIOTECHNOLOGY L. REP. 743, 743 (2005).

[286] *Id.*

[287] YALE UNIVERSITY, YALE UNIVERSITY FACULTY HANDBOOK 112 (2002), *available at* http://www.yale.edu/provost/handbook/faculty_handbook.pdf; *see also* Susan Haack, *Scientific Secrecy and "Spin": The Sad, Sleazy Saga of the Trials of Remune*, 69 LAW & CONTEMP. PROBS. 47 (2006) further discussing such examples.

ensure that their investigators have full participation in the design of the trials, unimpeded access to trial data, and the right to publish their findings."[288] Furthermore, a study of approximately 100 academic institutions found that only twelve percent of the universities specified limits on permissible delays in publication.[289] Drug companies often claim the contracts are not intended to suppress possibly negative trial findings, but to ensure data is properly analyzed before it is released.[290]

Nonetheless, this has not proven to always be the pharmaceutical industry's practice. For example, in connection with the pediatric antidepressant controversy, the only published article regarding a placebo controlled trial had concluded that the antidepressant under study was found to be safe and effective in treating adolescent depression.[291] However, there were four other similar trials with negative results that were never published.[292] Researchers who did have access to the data from these industry-sponsored trials were prohibited from publishing or speaking about the information because of the nondisclosure provisions contained in their contracts.[293] Although they may have wanted to alert the public regarding the potential for harm from these drugs, the researchers were not allowed to issue such warnings.

In another case involving the experimental HIV drug Remune, the manufacturer filed an arbitration proceeding attempting to prevent the publication of an article by two academic researchers involved in clinical trials of the medication and sought millions of dollars in damages.[294] The company,

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[288] Kevin A. Schulman et al., *A National Survey of Provisions in Clinical-Trial Agreements Between Medical Schools and Industry Sponsors*, 374 NEW ENG. J. OF MED. 1335, 1339 (2002).

[289] Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at U.S. Universities*, 284 JAMA 2203, 2203 (2000).

[290] Meier, *supra* note 202, at A1.

[291] E. Jane Garland, *Facing the Evidence: Antidepressant Treatment in Children and Adolescents*, 170 CAN. MED. ASS'N. J. 489, 489-91 (2004).

[292] *Id.*

[293] *Id.*

[294] *In re* Immune Response Sec. Litig., 375 F. Supp. 2d 983, 994 (S.D. Cal. 2005) (class action lawsuit brought by shareholders of the Immune Response Company

Immune Response, claimed the manuscript contained confidential clinical trial data owned by the drug maker, as well as failed to include positive information and comments from the research sponsor, in violation of the parties' contract. Nonetheless, The Journal of the American Medical Association went ahead with its scheduled publication of the piece, in which the authors concluded that clinical trials demonstrated Remune was ineffective.[295] The company publicly labeled the findings inaccurate, characterizing the JAMA article as "tabloid journalism," and promising that "the truth in the long run will come out."[296] However, in the end the results of the private arbitration proceedings were kept quiet, although it was reported that Immune Response was not awarded any damages in its action against the researches.[297]

It is impossible to determine how often disputes over control of clinical trial data occur between the companies that fund the studies and the researchers that conduct the trials. While anecdotal evidence suggests such controversies over publication may be quite common[298], researchers "so seldom stand up to their sponsors."[299] As a result, "there is no way to know how many negative studies have been suppressed—or worse, how many negative studies were converted to positives."[300]

While agreements delaying or preventing publication in all

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discussing the arbitration proceedings); *see also* Barry Meier, *Medicine's Data Gap: The Academic Connection*, N.Y. TIMES, Nov. 29, 2004, at A1.

[295] James O. Kahn, et al., *Evaluation of HIV-1 Immunogen, an Immunologic Modifier, Administered to Patients Infected With HIV Having 300 to 549 x 106/L CD4 Cell Counts* 284 JAMA 2193, 2193 (2000).

[296] *In re* Immune Response Sec. Litig., 375 F. Supp. 2d 983, 994 (S.D. Cal. 2005).

[297] *Zilch for Maker in AIDS Drug Suit*, S.F. CHRON., Sept. 11, 2001, at A10.

[298] *See* Thomas Bodenheimer, *Uneasy Alliance—Clinical Investigators and the Pharmaceutical Industry* (2006), *available at* http://www.heall.com/healingnews/may/clinical_investigators_and_pharmaceutical_industry.html.

[299] Katherine S. Mangan, *Company Seeks $10 Million from Scientist and University*, CHRON. HIGHER ED. Nov. 17, 2000, at A48, A50 (quoting Marcia Angell, Editor-in-Chief of the New England Journal of Medicine).

[300] *Id.*

likelihood are enforceable from a contractual formation standpoint, a strong argument can be made that they should not be enforceable on public policy grounds. These agreements essentially create a contractual gag order on information that may be vital to society's health and safety. Accordingly, an earlier version of the federal clinical trial results database bill that eventually became law prohibited a drug manufacturer from entering into a contract that prohibited or limited the ability of an individual to either discuss the findings of a clinical trial or publish the results.[301] Unfortunately, this provision was removed and replaced with a very weakly worded requirement to disclose merely the existence of such an agreement in a very narrow range of cases.[302] Despite the fact that Congress has failed to significantly restrain the use of these types of agreements, it still may be possible for the courts to provide some much needed constraints and send a strong signal to entities that insist on the inclusion and adherence to such data control provisions by clinical researchers.

C. Patents

With regard to patent protection, the pharmaceutical companies' arguments against disclosure of clinical trial results data are of a slightly different type. While drug companies' overriding concerns with trade secrets and contracts have been that the dissemination of study data would be a violation of such already established rights, pharmaceutical companies have maintained that the publication of trial information could have a negative effect on their ability to actually obtain patent protection in the first place. Pharmaceutical manufacturers claim that if a competitor were to gain access to this material, the rival could then utilize the data for its own patent applications, thus hindering their chances of even acquiring this form of intellectual property protection.[303] The drug industry contends that such "free riding" would ultimately impact efforts

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[301] Fair Access to Clinical Trials Act, S. 470, 109th Cong. (2005).

[302] *See* 42 U.S.C. § 282(j)(3)(C) (Supp. 2008).

[303] COMM. FOR ECON. DEV., *supra* note 3, at 14.

to commercialize the medications being tested, thereby reducing their incentives for undertaking original scientific research.[304] Consequently, they say this would lead to a decline in innovation to the detriment of society.[305] However, in light of the exceptionally aggressive patenting practices of the drug industry, as well as statutory changes to the law, these concerns are not especially convincing.

1. A Pharmaceutical Patent Portfolio

A patent typically provides its owner with the right to exclude others from making, using, or selling an invention for twenty years from the date of filing an application for such protection.[306] Despite the drug industry's claims that public access to clinical trial results data could jeopardize their capacity to acquire patent protection, the fact of the matter is that most pharmaceutical manufacturers have submitted their patent applications well before any clinical trial data involving human subjects would have actually been generated. More often than not, drug companies file for patent protection while the investigational drug compound is still in its earliest, preclinical testing stage.[307]

Such strategies do, however, create a different problem for the pharmaceutical companies. By filing so early in the drug development process, the patent could potentially expire even before the drug at issue could be commercially distributed. This is due to the fact that the intervals between patent issuance, clinical trial investigations, and finally FDA approval can be quite lengthy. However, in 1984 Congress passed the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), which attempted to provide a partial solution to the pharmaceutical industry's concerns. In order to account for the delay, the statute afforded patent holders the right to extend

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[304] *Id.*

[305] *Id.*

[306] 35 U.S.C. § 154 (2006).

[307] *See generally*, U.S. GOV. ACCOUNTABILITY OFFICE, *supra* note 42; Eisenberg, *supra* note 278.

their patents for up to five years, so long as the total time outstanding on the restored patent following FDA approval did not exceed fourteen years.[308] This change significantly reduced the likelihood that a pharmaceutical manufacturer would finally obtain FDA approval to market a drug and subsequently find that no sizeable period of time remained on the patent.

It is also worth noting that the drug industry is generally quite proficient at utilizing the patent system to obtain protection. It is not unusual for a single medication to be under multiple patents for various aspects of the underlying invention including its composition, a method of using the drug, and the process for manufacturing the pharmaceutical.[309] Furthermore, pharmaceutical companies have recently employed a wide variety of "evergreening" strategies to artificially extend the date a medication officially goes off-patent.[310] The combination of these tactics often allows a drug company to attain a dominant position in the marketplace, despite concerns to the contrary.[311]

2. ANDAs: Opening the Door to Generics

Prior to the passage of the Hatch-Waxman Act, generic pharmaceutical companies faced significant obstacles in entering the marketplace. In order to receive FDA approval, the generic firms were required to conduct their own clinical trials to support a new drug application. This was due to the fact that the FDA considered these generic versions of previously approved drugs "new drugs" themselves, thus necessitating evidence demonstrating the product's safety and efficacy.[312] However, the costs associated with testing were exceptionally high, and the opportunity to recover such expenses was limited.

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[308] 35 U.S.C. § 156 (2006).

[309] *See* Eileen M. Kane, *Molecules and Conflict: Cancer, Patents, and Women's Health*, 15 AM. U.J. GENDER SOC. POL'Y & L. 305 (2007) (examining various formats for patenting pharmaceuticals).

[310] Eisenberg, *supra* note 278, at 348-49.

[311] Kane, *supra* note 309, at 309.

[312] Response to Petition Seeking Withdrawal of the Policy Described in the Agency's "Paper" NDA Memorandum of July 31, 1978, 45 Fed. Reg. 82052 (Dec. 12, 1980).

An additional complication was the invariable delay between the time the original pharmaceutical company's patents on the drug expired and the generic firm could begin commercial distribution of their product. As conducting the requisite clinical trials would typically constitute patent infringement, generic firms could not begin carrying out these tests during the term of the brand-name pharmaceutical company's patents. Moreover, the inevitable wait associated with the FDA-review process created further time lag between the end of a brand-name pharmaceutical maker's patent term and the generic equivalent's entry to the market. However, the manufacturers of pioneer drugs were less than sympathetic to the plight of the generic firms, arguing the inadvertent marketplace exclusivity produced by the circumstances was not inequitable in light of the fact the FDA approval process often consumed many years of patent life.[313]

Nonetheless, in addition to extending the brand-name pharmaceutical makers patent term for up to five years as discussed above, the Hatch-Waxman Act made further changes to allow for easier entry into the marketplace by generic pharmaceutical makers. Instead of requiring such companies to complete their own clinical trials to demonstrate safety and efficacy, they would now be allowed to rely on the prior research from the brand-name manufacturer to market their essentially duplicate drug.[314] As a result, the only new studies the generic manufacturers would need to conduct were clinical tests to prove the proposed drug was "bioequivalent" to the previously approved drug.[315]

Moreover, as carrying out such experiments would typically constitute patent infringement, the Hatch-Waxman Act also added a statutorily based research exemption to supplement the common law experimental use privilege.[316] This provision offers broad exemption from traditional infringement liability by allowing the making or using of a patented invention, so long as

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[313] *See* Eisenberg, *supra* note 278, at 356-57.

[314] 21 U.S.C. § 355(j) (2006).

[315] *Id.*

[316] 35 U.S.C. § 271(e)(1) (2006).

such investigations are for purposes related to the development and submission of information under federal law which regulates the use of drugs.[317] Consequently, a generic manufacturer can now complete the required studies during the term of the brand-name pharmaceutical maker's patents. Additionally, the company can submit a streamlined application called an Abbreviated New Drug Application ("ANDA") even before the patents associated with the pioneer drug have expired.[318] This allows a generic drug maker to also effectively avoid the delay normally associated with the FDA approval process. Nonetheless, the generic manufacturer will not be able to enter the marketplace until all applicable patents and related extensions of the brand-name pharmaceutical maker have actually expired.

It should be noted that although an ANDA applicant is essentially permitted to make use of a brand-name pharmaceutical maker's prior clinical trial results, the generic drug company normally does not actually have access to this data. Instead, the generic drug manufacturer is able to take advantage of the earlier research more or less indirectly.[319] However, for an FDA applicant that plans to make a modification to the brand-name manufacturer's formulation thus disqualifying it from the ANDA process, the Hatch-Waxman Act also included an additional section which permits such a drug maker to explicitly rely in whole or in part on another company's data.[320]

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[317] *Id.* Recently, this safe harbor language was interpreted quite broadly by the U.S. Supreme Court to cover a full range of pre-clinical activities, including experimentation on drugs not ultimately the subject of an FDA application. Furthermore, the Court held that the statutory exemption is not limited to only studies relating to the safety of the drug in human subjects. Merck KGaA v. Integra Lifesciences, 545 U.S. 193 (2005).

[318] 21 U.S.C. § 355(j)(2)(A)(iv) (2006).

[319] *See* JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 311 (2005).

[320] *Id.* at 312 (illustrating such a scenario by means of the example of an approved drug utilizing an active ingredient with a particular salt formation and a generic firm that wants to market a generic version of the approved drug with the same active ingredient but using a different salt formulation; in such a case the generic firm may be unable to file an ANDA because the proposed active ingredient will not be identical to that of the originally approved medication.)

3. Section 505(b)(2): Borrowing Data

Section 505(b)(2) of the Hatch-Waxman Act allows for applications in which one or more of the investigations utilized in order to acquire FDA approval "were not conducted by or for the applicant."[321] Section 505(b)(2) differs from a traditional NDA because the applicant does not have a "right of reference," defined as "the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an application."[322] Typically, a Section 505(b)(2) applicant is drawing upon clinical trial results appearing in published scientific literature.[323]

Not surprisingly, the availability of Section 505(b)(2) generally leads to significant costs savings. The law essentially allows the applicant to "free ride" at the expense of other drug companies who had previously incurred the costs and risks associated with conducting their own trials. Nonetheless, despite objections by the pharmaceutical trade to the contrary, the FDA has somewhat surprisingly stated in drug industry guidance documents that such use of previous research "was intended to encourage innovation without creating duplicate work."[324] Further, the FDA has maintained that both Section 505(b)(2) and the ANDA process reflect the same principles, namely that "it is wasteful and unnecessary to carry out studies to demonstrate what is already known about a drug."[325] However, also similar to ANDA applicants, Section 505(b)(2) applicants must observe the term of any applicable patents covering their pharmaceutical, consequently requiring the expiration of such intellectual property protection before they

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[321] 21 U.S.C. § 355(b)(2) (2006) (codifying Section 505(b)(2) of the Hatch-Waxman Act).

[322] 21 C.F.R. § 314.3(b) (2008).

[323] FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: APPLICATIONS COVERED BY SECTION 505(b)(2) 2 (1999). It should be pointed out that this is usually without the benefit of the full underlying raw data from the studies. *Id.* This is due to the fact that pharmaceutical companies generally view this information as confidential material and fiercely resist attempts at complete disclosure.

[324] *Id.* at 3.

[325] *Id.*

may begin commercially distributing their product.

4. Evaluating the Arguments

The pharmaceutical industry's concerns that the public disclosure of clinical trial results, particularly the underlying raw data, will negatively impact their ability to obtain patents appear to be quite exaggerated. Most drug companies obtain patents very early on in the drug development process prior to beginning clinical trials. This protection will prevent any attempts by a competitor to enter the marketplace until the expiration of the term of an applicable patent or market exclusivity,[326] regardless of whether they have access to the results of another company's clinical trial data. While it is possible such data could be valuable to a competitor to assist in structuring their research strategy, as discussed above most pharmaceutical companies are already quite aware of the development activities of their fellow members in the drug industry.

Furthermore, the company that originally sponsored a study would not lose all of its benefits if the trial results are subsequently revealed, as it would have had a multi-year head start in analyzing the data, as well as formulating plans to act upon said information.[327] As one commentator explained, "By permitting substantial free-riding even without access to the underlying data, the Hatch-Waxman Act has thus taken the wind out of the sails of an argument against data disclosure that rests upon protection from free riders."[328] Lastly, in attempting to prevent potential commercial loss, it is also important not to lose sight of the significant societal benefits that could be gained

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[326] Market exclusivities prevent the FDA from approving, or in some cases even accepting, an application for a competing drug compound for a stated period of time. These exclusivities relate to new chemical entities (five years), new clinical studies (three years), generic drugs (180-day exclusivity for first ANDA on previously approved brand-name drug), orphan drugs (seven years), and pediatric studies (extending exclusivity or patent protection on the innovator drug for six months). *See* THOMAS, *supra* note 319, at 348-73.

[327] COMM. FOR ECON. DEV., *supra* note 3, at 15.

[328] Eisenberg, *supra* note 278, at 382.

as a consequence of providing access to clinical trial results.

D. Competitive Necessity

The pharmaceutical industry has consistently asserted that preserving the confidentiality of clinical trial results is absolutely essential to ensuring their capacity to profit from the research they themselves conduct or financially sponsor.[329] Without the ability to potentially generate revenue as a result of these clinical studies, drug companies argue that there would be little incentive to engage in medical research in the first place.[330] Moreover, the resulting reduction in necessary information production "could be extremely dangerous and have a detrimental effect on health care for years to come."[331]

Despite the pharmaceutical industry's broad claims to the contrary, there is no credible support for the position that maintaining the secrecy of clinical trial data is necessary to promote clinical research or foster innovation.[332] As the WHO's International Clinical Trials Registry Platform group concluded following formal consultations with representatives from the drug industry, medical community, and scientific field, "there is no convincing evidence that disclosure threatens competition and hence innovation. Indeed, openness might promote rather than stifle innovation."[333]

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[329] *See e.g.*, Janene Boyce, *Disclosure of Clinical Trial Data: Why Exemption 4 of the Freedom of Information Act Should Be Restored*, 2005 DUKE L. & TECH. REV. 3 (2005); Howard L. Dorfman & Linda Pissott Reig, *Avoiding Legal and Ethical Pitfalls of Industry-Sponsored Research: The Co-Existance of Research, Scholarship and Marketing in the Pharmaceutical Industry*, 59 FOOD & DRUG L.J. 595 (2004); Scott M. Lassman, *Transparency and Innuendo: An Alternative to Reactive Over-Disclosure*, 69 LAW & CONTEMP. PROBS. 69 (2006).

[330] *See e.g.*, Boyce, *supra* note 329; Dorfman & Reig, *supra* note 329; Lassman, *supra* note 329.

[331] Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 623 (2007).

[332] *See* Joel Lexchin, *The Secret Things Belong Unto the Lord Our God: Secrecy in the Pharmaceutical Arena*, 26 MED. & L. 417 (2007); Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L.REV. 837 (1980); Sam Palmisano, *The Information Puzzle*, NEWSWEEK INT'L, Nov. 28, 2005, at 54.

[333] Sim et al., *supra* note 283, at 1631.

Greater dissemination of clinical trial results would likely reduce unnecessary duplication of research and thus improve its overall efficiency.[334] Future studies could be informed by prior research which would decrease the probability of failure. Improvements in the drug development process would likely produce a considerable reduction in the cost of pharmaceutical research.[335] A fairly recent study estimated that increasing the success rate from the current 21.5% to 33.3% would yield a reduction of $221 million in capitalized cost per new drug candidate.[336]

Additionally, disclosure of research results could also enhance a drug company's financial outlook in yet another possibly unexpected way. Industry experts identify the inability to recruit study participants as the single greatest concern in the drug development process.[337] This is due to the fact that such problems can slow the approval process which can ultimately cause substantial financial losses.[338] One estimate places the average cost to a drug manufacturer for each day's delay in obtaining FDA approval at an astounding $1.3 million dollars.[339]

The current public perception of the pharmaceutical industry could easily jeopardize clinical trial enrollments. However, the increased transparency associated with releasing study data may very well improve the public's perception of the benefits associated with participation in clinical trials. Consequently, this may positively affect patient accruals to the pharmaceutical industry's advantage.

Accordingly, not only would drug companies recognize considerable financial savings, but also society would likely benefit from an acceleration in the discovery of new

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[334] *Id.*

[335] Michael Dickson & Jean Paul Gagnon, *The Cost of New Drug Discovery and Development*, 4 DISCOVERY MED. 172, 178 (2004).

[336] *Id.*

[337] Trudo Lemmens, *Commercialized Medical Research and the Need for Regulatory Reform* (Univ. of Toronto Legal Studies Series, Research Paper No. 967393, 2007).

[338] *Id.*

[339] *See* Bodenheimer, *supra* note 298.

treatments.[340] In fact, the FDA has even expressly stated that there is "an urgent need to . . . enhance collaboration among the government, industry, and academia."[341] The agency reported that pharmaceutical companies have predominantly been submitting NDAs for variations on existing drugs instead of innovative drugs.[342] The FDA maintains further cooperation and sharing is essential to the development of pioneering treatments.[343] This is due in large part to the fact that scientific breakthroughs rarely occur in complete isolation, but are usually the result of advancements made on the pioneering discoveries of earlier researchers.[344] The ability to access and utilize information is critically important to societal progress.[345]

E. Patient Confusion

Ironically, pharmaceutical companies also claim their reluctance to release clinical trial results is actually due to their concern for patient welfare. The drug industry argues the dissemination of results from a single study could mistakenly depict safety or efficacy hazards which multiple trials afterward would reveal were a mere aberration and clearly not present. In the interim, however, patients may suffer unnecessary distress potentially leading to the discontinuation of critically important medication. Additionally, the disclosure of such negative clinical trial findings risks the creation of an unmerited strain on the doctor-patient relationship due to decreases in confidence over health provider competency.[346] Moreover, drug companies

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[340] *See* Krleža-Jerić et al., *supra* note 20.

[341] U.S. GOV. ACCOUNTABILITY OFFICE, *supra* note 42, at 2; FOOD & DRUG ADMIN., *supra* note 3.

[342] U.S. GOV. ACCOUNTABILITY OFFICE, *supra* note 42, at 2; FOOD & DRUG ADMIN., *supra* note 3.

[343] U.S. GOV. ACCOUNTABILITY OFFICE, *supra* note 42, at 2; FOOD & DRUG ADMIN., *supra* note 3.

[344] *See* Christine D. Galbraith, *A Panoptic Approach to Information Policy: Utilizing a More Balanced Theory of Property in Order to Ensure the Existence of a Prodigious Public Domain*, 15 J. INTELL. PROP. L. 1, 3 (2007).

[345] *Id.*

[346] Celia B. Fisher, *Clinical Trials Results Databases: Unanswered Questions*, 311 SCIENCE 180, 180-81 (2006).

contend the administrative resources that would inexorably be required to fulfill reporting obligations may raise the costs of pharmaceuticals.[347] The drug industry asserts this type of highly technical information is simply not the sort of material that can be properly evaluated by an untrained individual.

However, it seems as if the pharmaceutical companies may have improperly discounted the intellectual abilities of patients today. The testimony of a doctor at a congressional hearing on the FDA approval process provided the following contrary characterization: "You would be amazed how sophisticated a lot of patients are, and again, others on the panel can speak to this, who come to physicians [having] really done a tremendous amount of research and do know a lot."[348] The Internet has already provided the public with access to vast amounts of medical information. Moreover, healthcare has become far more of a collaborative process between doctor and patient, rendering the rather paternalistic practice of viewing a physician as the unquestioned authority on medical issues virtually obsolete. To the extent that patients need to be alerted to the possibility that results from a single study may not necessarily provide a comprehensive estimation of the true value of a particular treatment, an appropriately worded disclaimer would seem a suitable approach to adequately advising the public. In the end, the purported disadvantages associated with disseminating results information are not compelling enough to justify preventing patients from accessing information that could allow them to make better educated decisions concerning their own health and welfare.

VII. ADDITIONAL ARGUMENTS IN SUPPORT OF DISCLOSURE

Leaving aside the many shortcomings associated with the arguments advanced for limiting any sort of further disclosure of clinical trial results, there are compelling independent

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[347] *Id.*

[348] *FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions,* 109th Cong. (2005) (testimony of Dr. David Fassler).

justifications for further release of such data. Changes to the FDA's funding structure, in addition to the dramatic increase in private sponsorship of research studies, collectively contribute to a state of affairs that is in desperate need of enhanced transparency. Moreover, the revelation that clinical trials with negative outcomes are far less likely to be published makes improved access to the results of all clinical trials even more critical. Lastly, in order to allow for informed decision making by patients and their doctors, as well as comply with ethical norms, full disclosure of clinical trial results must occur.

A. PDUFA & FDA Transparency Issues

In response to drug industry's complaints that the FDA was taking far too long to review and approve new drug applications, Congress passed the Prescription Drug User Fee Act (PDUFA) in 1992.[349] The legislation established a program through which additional staff would be hired with the objective of reducing approval times.[350] This would be funded by fees paid by the pharmaceutical companies in connection with the submission of their applications for evaluation.[351] The Act also provided for the establishment of performance goals for the agency, including completing review of a specified percentage of applications within particular time frames.[352] Additionally, the statute provided that the funds generated by the user fee program

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[349] Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491.

[350] *Id.*

[351] *Id.* The PDUFA also contained a provision that required reauthorization every five years to continue. Such action was taken in 1997 as part of the Food and Drug Administration Modernization Act, in 2002 in connection with the Public Health and Bioterrorism Preparedness and Response Act, and most recently in 2007 with the Federal Drug Administration Amendments Act. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296; Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594; Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.

[352] Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491; U.S. GOV. ACCOUNTABILITY OFFICE, *supra* note 42, at 10 (explaining that current goals state that the FDA should complete its intial review and act on ninety percent of all priority NDAs within six months and ninety percent of all standard NDAs within ten months).

would not be used for any other administrative purposes.[353]

PDUFA in some respects could be considered a success. For drugs receiving priority review,[354] the median length for approval decreased from 14.9 months in 1997 to 6.7 months in 2003. Similarly, standard review times were also reduced from 27.2 months to 23.1 during the same time period. Nonetheless, the Act also appears to have created some very problematic conflicts of interest.

In connection with a congressional hearing examining the Vioxx controversy, a director in the FDA's drug safety division described the existence of a culture in which the FDA "views the pharmaceutical industry it is supposed to regulate as its client, over-values the benefits of the drugs it approves and seriously under-values, disregards and disrespects drug safety."[355] A study prepared by the General Accounting Office (GAO) at the request of the Senate's Committee on Health, Education, Labor and Pensions, found that as a result of PDUFA, the "FDA reduced staffing levels for non-PDUFA activities each year, leaving the agency fewer resources to perform its other responsibilities" including safety-related activities. The GAO report also concluded that the legislation had "contributed to increased workload, high turnover rates, [as well as] reduced training time for scientists and medical officers on review teams."[356]

Moreover, a survey conducted regarding the PDUFA further echoes such concerns. According to a report prepared by the Office of the Inspector General, which was based upon responses from almost 400 FDA scientists, new drug reviewers in the FDA's Center for Drug Evaluation and Research (CDER) have been pressured to recommend approval of a drug even if they have reservations.[357] The 2002 study also found that

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[353] Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491.

[354] Drugs receive priority review only if they are deemed to offer a therapeutic advantage over existing medications. *See, e.g.*, Okie, *supra* note 130, at 1063.

[355] *FDA, Merck and Vioxx: Putting Patient Safety First: Hearing Before the S. Comm. on Finance,* 108th Cong. (2004).

[356] Okie, *supra* note 130, at 1063 (discussing the Office of Inspector Gen., FDA's Review Process for New Drug Applications: A Management Review 12 (2003)).

[357] *Ensuring Drug Safety: Where Do We Go From Here?: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions,* 109th Cong. (2005) (statement of the

almost one-fifth claimed to have been pushed to approve a new drug despite the existence of safety, efficacy, or quality questions.[358] Additionally, with respect to drugs that were granted priority review, more than half of the respondents stated they were not given enough time to conduct an in-depth, scientific review.[359]

These findings raise serious issues regarding the quality of FDA review and its corresponding impact on public safety. Moreover, this lends further substantiation to the need for disclosure of full clinical trial results to allow for additional scrutiny of the FDA's approval decisions. Such transparency would help ensure that public interest is always the first priority.[360]

B. Impact of Industry Influence on Clinical Trials

It is estimated that more than eighty percent of all clinical trials are now funded by for-profit companies.[361] The consequences of this tidal shift away from government support of research studies is still not yet entirely clear, however, evidence is beginning to mount regarding the myriad of ways in which pharmaceutical industry sponsorship affects the outcome and reporting of clinical trials. The results of such influence can appear even in the earliest stages of a research study in connection with the way in which a company structures the drug trial.[362] For example, one reported instance of this type of activity occurred in connection with an investigational pain medication.[363] Initial data indicated that the sponsor's drug had an increased risk for heart attacks when evaluated against an

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American Society of Health-System Pharmacists citing OFFICE OF INSPECTOR GEN., FDA'S REVIEW PROCESS FOR NEW DRUG APPLICATIONS: A MANAGEMENT REVIEW (2003)).

[358] OFFICE OF INSPECTOR GEN., FDA'S REVIEW PROCESS FOR NEW DRUG APPLICATIONS: A MANAGEMENT REVIEW 12 (2003).

[359] *Id.* at 10.

[360] *See* Lexchin, *supra* note 332, at 417.

[361] *See* Vedantam, *supra* note 14, at A1.

[362] Press Release, AAAS, Pharma Facing Tough Challenges, Speakers Say at AAAS S&T Forum (May 17, 2007), *available at* http://www.aaas.org/news/releases/2007/0517stpf.shtml (last visited Apr. 4, 2009).

[363] *Id.*

existing pain reliever.[364] Consequently, the pharmaceutical company altered the structure of the trial, replacing the original comparison drug with a different medication in its class that was considered much more risky, maximizing the potential for a favorable outcome.[365] As one commentator notes, by utilizing these sorts of tactics, "You can usually figure out a trial that gets to 'yes.'"[366]

Additional reports provide further evidence that commercial sponsorship of trials can result in reduced objectivity and a potentially biased presentation of evidence concerning the benefit to risk profile of the product.[367] For example, a review of clinical trials funded by pharmaceutical companies comparing psychiatric medications showed that in ninety percent of the clinical investigations, the outcome favored the sponsor's drug.[368] However, if a medication did well against a competitor in one particular trial, it invariably came in second when the clinical investigation was instead funded by the competitor.[369] Similarly, an analysis of seventy articles on clinical trials evaluating the safety of drugs utilized to treat cardiovascular disorders demonstrated a comparable effect. Ninety-six percent of the authors of articles that were

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[364] *Id.*

[365] *Id.*

[366] *Id.* (statement of Dr. Deborah Zarin, Director of the ClinicalTrials.gov registry). For other examples of such conduct related to trial structure *see* Paula A. Rochon et al., *A Study of Manufacturer-Supported Trials of Nonsteroidal Anti-Inflammatory Drugs in the Treatment of Arthritis,* 154 ARCHIVES INTERNAL MED. 185 (2006) (dosing of the pharmaceutical manufacturer's drug was higher than that of the comparison drug) and Helle Krogh Johansen et al., *Problems in the Design and Reporting of Trials of Antifungal Agents Encountered During Meta-Analysis,* 282 JAMA 1752 (1999) (vast majority of company sponsored trials designed so that drugs under study were all taken orally; however, the comparison medication was known to poorly absorb and as such was traditionally only given intravenously).

[367] *FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 109th Cong. 36-41 (2005) (testimony of Dr. Thomas R. Fleming).

[368] Stephen Heres, et al., *Why Olanzapine Beats Risperidone, Risperidone Beats Quetiapine, and Quetiapine Beats Olanzapine: An Exploratory Analysis of Head-to-Head Comparison Studies of Second Generation Antipsychotics,* 163 AM. J. PSYCHIATRY 185, 185 (2006); *see also* AAAS, supra note 362 (statement of Shannon Brownlee).

[369] AAAS, *supra* note 362.

supportive of the use of the drug under investigation had financial relationships with the manufacturer of the pharmaceutical, while only thirty-seven percent of those critical of the medication had industry sponsorship.[370] Furthermore, a large survey of more than a thousand original research studies found a "statistically significant association between industry sponsorship and pro-industry conclusions."[371]

Issues also frequently arise in connection with the publication of articles related to industry-sponsored clinical trials. This is due in large part to the fact that industry sponsors often assert ownership over the data collected in connection with the studies they fund[372] and consequently impose restrictions on publishing and the sharing of research results.[373] As such, "[i]f a test suggests that a drug is effective in treating a certain condition, the company will push to get its results published in a prestigious journal. If the results reflect poorly on the drug, they often never appear in public."[374]

Likewise, to the extent the study results are a mixture of positive and negative outcomes, industry-funded investigators may downplay any unfavorable data or selectively report the findings. For example, in one study researchers reported that "most adverse events were not serious" when in actuality seven children were hospitalized as a result of side-effects attributable to the medication under examination.[375] In another case involving the pain reliever Celebrex, the Journal of the American Medical Association ("JAMA") published an article highlighting the medication's beneficial safety profile.[376] The

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[370] Henry Thomas Stelfox, et al., *Conflict of Interest in the Debate Over Calcium-Channel Antagonists,* 338 NEW ENG. J. MED. 101, 101 (1998).

[371] Justin E. Bekelman, et al., Scope and Impact of Financial Conflicts of Interest in Biomedical Research—A Systematic Review, 289 JAMA 454, 454 (2003).

[372] *See infra* Part VI discussing the frequent use of contracts in an attempt to delineate data ownership.

[373] Bekelman, *supra* note 371, at 454.

[374] Gardiner Harris, *Spitzer sues a Drug Maker, Saying It Hid Negative Data*, N.Y. TIMES, June 3, 2004, at A1.

[375] AAAS, *supra* note 362 (statement of Shannon Brownlee).

[376] Fred E. Silverstein et al., *Gastrointestinal Toxicity with Celecoxib vs Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis: The CLASS*

authors of the report claimed that the clinical trial data demonstrated that the drug was associated with significantly lower rates of gastrointestinal ulcers when compared with two older medications.[377] However, it was only after the piece appeared in print that JAMA's editors learned that the authors of the study had utilized only the data from the first six months of the trial and failed to disclose the actual length of the clinical investigation was in fact twelve months. It turned out that the data from the year-long study showed no statistical advantage between Celebrex and the comparison drugs.[378]

Furthermore, as part of a pharmaceutical company's publication strategy, articles on trial results are increasingly prepared by medical information companies.[379] This practice known as "ghost writing" entails providing nearly finished manuscripts to prestigious academics to put their names on the pieces prior to publication, individuals who often have not had any involvement whatsoever in the clinical research itself.[380] For example, in connection with marketing the drug Vioxx, a study in the Journal of the American Medical Association identified dozens of articles actually drafted by employees of the drug manufacturer Merck, but which attributed authorship to prestigious doctors who did not disclose industry financial support.[381]

Not surprisingly, numerous studies have shown that articles appearing in published literature have a disproportionately high quantity of positive outcomes.[382] This

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Study: A Randomized Controlled Trial., 284 JAMA 1247, 1247 (2000).

[377] *Id.*

[378] Susan Okie, *Missing Data on Celebrex - Full Study Altered Picture of Drug,* WASH. POST, Aug. 5, 2001, at A11.

[379] Lemmens, *supra* note 337.

[380] *Id.*; *see also* Stephanie Saul, *Ghostwriters Used in Vioxx Studies, Article Says*, N.Y. TIMES, April 15, 2008, at A1.

[381] Joseph S. Ross, et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib,* 299 JAMA 1800, 1800 (2008).

[382] *See e.g.*, Robert John Simes, *Publication Bias: The Case for an International Registry of Clinical Trials*, 4 J. CLINICAL ONCOLOGY 1529 (1986); Kay Dickersin et al., *Factors Influencing Publication of Research Results*, 267 JAMA 374 (1992); Kay Dickersin, *The Existence of Publication Bias and Risk Factors for its Occurrence*, 263 JAMA 1385 (1990).

propensity on the part of investigators to submit manuscripts for publication based upon the positive results of the study findings is often referred to as "publication bias."[383] Numerous studies have documented this "clear correlation between non-publication and lack of significant findings."[384] While journal editors may have some responsibility for this situation, the unwillingness of investigators to submit inconclusive or negative research results for publication appears to be the main factor.[385] Furthermore, trials with positive results are also generally published more quickly, on average two to three years earlier than those with inconclusive or negative results.[386] Consequently, the cumulative impact of these issues associated with industry sponsorship of clinical trials is a quite unbalanced picture of the safety profile associated with a particular drug. Knowledge of the full range of risks and benefits is essential for physicians and patients to make truly informed decisions regarding proper medical care. Access to both negative and positive trial results is crucial to ensuring the most appropriate treatment is selected for any given individual. Additionally, if detailed information on all studies were available, it could be utilized by scientists to perform meta-analyses of all the existing studies that have been conducted involving a particular medication. The aggregation of raw data would allow for earlier detection of significant adverse effects.[387] As such, it is absolutely essential that full trial protocols and their attendant results be made publicly accessible to ensure that this distortion of available data does not harm patients.

C. Clinical Trials and Ethical Norms

Clinical research involving human subjects can only be

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[383] Kay Dickersin, *The Existence of Publication Bias and Risk Factors for its Occurrence*, 263 JAMA 1385, 1385 (1990).

[384] Jennifer L. Gold and David M. Studdert, *Clinical Trial Registries: A Reform that is Past Due*, 33 J. L. MED. & ETHICS 811 (2007).

[385] *Id.*

[386] S. Hopewell et al., *Time to Publication for Results of Clinical Trials*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS, Issue 2 (2007).

[387] Zarin et al. *supra* note 195, at 2113.

justified if the experiments conducted produce generalizable knowledge.[388] Many in the medical community have interpreted this ethical principle to require the public disclosure of all research results.[389] This is due to the fact that individuals voluntarily participating in clinical trials expect information obtained from the study will be available to future patients and ultimately improve medical care.[390] Nonetheless, this is not possible to the extent trial results are concealed or remain hidden.

Moreover, if research results never become public, study participants may have risked the harm of the treatment with no recognizable benefit. This is in complete conflict with ethical codes that prohibit human subjects from being unnecessarily exposed to research harms.[391] The sponsor of a clinical trial therefore has an obligation to acknowledge the contribution of the participants by ensuring that study results are in the public domain.[392] Additionally, to the extent that studies are not published, there exists a very real possibility the same mistakes may be repeated by other companies who are also developing drugs with the same or similar properties. Particularly when there are adverse effects related to the investigative medications, it seems immoral not to report such findings to prevent future trial participants from needlessly being subjected to harm.[393]

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[388] The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23, 192 (Apr. 18, 1979).

[389] *See e.g.*, David Korn & Susan Ehringhaus, *Principles for Strengthening the Integrity of Clinical Research*, 1 PLOS CLINICAL TRIALS e1 (2006); Drazen & Wood, *supra* note 21, at 2809.

[390] *See* Korn & Ehringhaus, *supra* note 389, at 2-3; Drazen & Wood, *supra* note 21, at 2809.

[391] *See* World Med. Ass'n, *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 284 JAMA 3043 (2000); The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192 (Apr. 18, 1979).

[392] Jeffrey M. Drazen et al., *Open Clinical Trials*, 357 NEW ENG. J. MED. 1756, 1756 (2007).

[393] *Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation: Before the S. Comm. on Health, Education, Labor, and Pensions*, 110th Cong. 2 (2006) (testimony of Dr. Steven E. Nissen).

Individuals who agree to participate in clinical trials typically assent to treatment in the belief that they are actually contributing to medical knowledge.[394] If, however, the insight obtained from the study is never reported, ethical issues also arise over whether the patient was truly able to provide the obligatory informed consent.[395] This is particularly concerning where drug companies are "gaining financially from public involvement in trials, but refusing to reciprocate by making information from industry-sponsored trials generally available."[396] Ethical guidelines clearly require that the rights of clinical trial participants must take precedence over commercial interests.[397] Furthermore, failure to do so is simply not defensible, since as between study participants and drug industry sponsors, it is very obvious who is taking the greater risk.[398]

VIII. CONCLUSION

It is imperative that the pharmaceutical industry recognize that without clinical trial participants they would not be able to generate the findings necessary to potentially obtain FDA approval on their products. Even more importantly, however, patients enrolled in such studies place their trust in these companies to ensure their safety, as well as advance medical knowledge. This cannot happen when drug companies and the FDA fail to disclosure meaningful clinical trial results. As such, genuine statutory reform to make the clinical trials process more transparent must occur so that proper protection is provided for all patients requiring medical care.

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394 Dickersin & Rennie, *supra* note 185, at 517.

395 *Id.*

396 *Id.*

397 Sim et al., *supra* note 283, at 1632 (citing World Med. Ass'n, *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 284 JAMA 3043 (2000) and Nuremberg Code, *reprinted in* 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 (1949), *available at* http://ohsr.od.nih.gov/guidelines/nuremberg.html).

398 Drazen et al., *supra* note 392, at 1756.

FIRE SALE: THE SITUATIONAL ETHICS OF ANTITRUST LAW IN AN ECONOMIC CRISIS

*Sharon E. Foster**

I. INTRODUCTION

The current economic crisis is based, in part, upon "a dizzying array of innovative products" generated by the financial services sector of the economy after deregulation of the banking and investment industries.[1] When the "innovative products" bubble burst, the financial services sector went into an economic free-fall with stock prices in this sector falling significantly. This, in turn, provided an opportunity to implement the famous investment maxim, "Buy when there is blood on the streets."[2] And so they did. Bank of America bought Countrywide and Merrill Lynch;[3] J.P. Morgan bought Bear Stearns;[4] and Wells

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[1] Nelson D. Schwartz & Julie Creswell, *What Created this Monster?*, N.Y. TIMES, Mar. 23, 2008, at BU1. The financial services sector includes commercial banking, investment banking, merchant banking, brokerage and other securities and insurance activities.

[2] Nawar Alsaadi, *Unique Opportunity in Blackstone Group*, SEEKING ALPHA, Feb. 10, 2008, http://seekingalpha.com/article/63853-unique-opportunity-in-blackstone-group (attributing quote to Philippe Rothschild).

[3] James R. Hagerty & Valerie Bauerlein, *Credit Crunch: BofA Sets Closing Date for*

Fargo acquired Wachovia.[5] Across the pond, Lloyds bought HBOS, but not without some concern that European competition law[6] would need to change to smooth the way for a regulatory merger of this size.[7] Yet, back in the United States, it seemed that no one was concerned about the antitrust implications of these mega-mergers, or at least not noticeably so.

One might attribute this apathy to the dexterity with which United States antitrust law rises to the challenge of ever changing economic realities. On the other hand, one might attribute the apparent lack of concern to the situational ethics philosophy that runs through United States antitrust law. Some might say that the alleged dexterity of United States antitrust law is the same thing as situational ethics in the law. However one wishes to characterize antitrust law, in the current economic crisis, it seems apparent that the United States is invoking situational ethics first and will worry about categorical imperatives, like concentration of power concerns and freedom to compete, later.

II. SITUATIONAL ETHICS

It should come as little surprise to many familiar with the antitrust laws of the United States that a pragmatic approach of flexibility to address different facts and circumstances is often preferred to a rigid approach. Examples include the preference of a rule of reason approach over adopting per se rules to determine if there is a restraint on trade,[8] and considering economic efficiencies in determining if a merger should be

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Countrywide Purchase, WALL ST. J., Jun. 20, 2008, at C2; Matthew Karnitschnig, Carrick Mollenkamp & Dan Fitzpatrick, *Bank of America to Buy Merrill*, WALL ST. J., Sept. 15, 2008, at A1.

[4] *J.P. Morgan, Bear Near Completion*, WALL ST. J., Apr. 9, 2008 at C4.

[5] Dan Fitzpatrick, *Three Banks Complete Deals*, WALL ST. J., Jan. 2, 2009 at C3.

[6] James Q. Whitman, *Consumerism Versus Producerism: A Study in Comparative Law*, 117 YALE L.J. 340, 372 (2007). European competition law is the equivalent of United States antitrust law.

[7] Steve Slater, *Lloyds TSB Wraps Up HBOS Deal*, INT'L HERALD TRIB., Sept. 18, 2008, at Finance 15.

[8] Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 127 S. Ct. 2705, 2713 (2007).

approved.[9] But does such an approach undermine certainty in the law, stare decisis, and ethical considerations present in categorical values? Are we a nation of situational ethicists willing to cast aside, perhaps temporarily, one of the principle tenets of our economic system: that freedom to compete is necessary to support our community's standards?[10] Specifically, would the mega-mergers of financial service corporations have been condoned by government regulators absent such critical times?

In practice, many people subscribe to what is called situational ethics.[11] In the legal world, courts often recognize that different facts and circumstances may lead to different results in cases applying the same laws.[12] Situational ethics allows for the contingent nature of human relationships, infinite possibilities, "the dynamic nature of interacting events, and the evolving contextual circumstances."[13] This nimbleness may be essential to economic survival in times of financial crisis.

A situational ethicist is also aware of community standards as reflected in the laws, but may be "willing to compromise those standards if doing so would seem to better serve a greater good or purpose."[14] Accordingly, if community standards are reflected

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[9] Dep't of Justice & Fed. Trade Comm'n, 1992 Horizontal Merger Guidelines (1992) (rev'd, Apr. 8, 1997), *available at* http://www.usdoj.gov/atr/public/guidelines/hmg.pdf [hereinafter Merger Guidelines].

[10] Certainly, there are those who may question whether freedom to compete is necessary for the United States' community standards. That said, courts seem to place it at or near that level. *See, e.g.*, Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc., 473 U.S. 614, 651 (1985) (quoting United States v. Topco Assocs., 405 U.S. 596, 610 (1972)).

[11] Randall Grometstein, *Prosecutorial Misconduct and Noble-Cause Corruption*, 43 CRIM. L. BULL. 63 (2007).

[12] For example, compare *Dr. Miles Medical Co. v. John D. Park & Sons Co.*, 220 U.S. 373 (1911), holding that vertical agreements to fix minimum resale prices are a per se violation of antitrust laws, with *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 127 S. Ct. 2705 (2007), holding that vertical agreements to fix minimum resale prices are not a per se violation of antitrust laws.

[13] Kam C. Wong, *Retribution and Corporate Crime*, 42 CRIM. L. BULL. 397, 412 (2006).

[14] Shawn E. Peterson, *A Comprehensive National Policy to Stop Human Cloning: An Analysis of the Human Cloning Prohibition Act of 2001 with Recommendations for Federal and State Legislatures*, 17 NOTRE DAME J.L. ETHIC & PUB. POL'Y 217, 260 (2003);

in laws and economic policies promoting free competition, a situational ethicist would be willing to restrain competition on a temporary basis in order to avoid a complete community collapse.[15] It is the "contextual appropriateness" of the act, not whether the act is good or evil, which is the focus for a situational ethicist.[16] Rules are not ignored; however, circumstances allow deviation, provided the greater good is served.[17] Of course, the down side to open-ended situational ethics is ad hoc judgment, a lack of categorical rules which provide certainty, and a sense of a lack of fairness in the legal system.[18]

As we are experiencing today, and have experienced in the past, antitrust law in the United States leans more towards situational ethics than categorical imperatives. This flexibility may prove critical in the current economic crisis; however, the long-term greater good of the community standards, as reflected in antitrust policy, would seem to dictate, when the crisis is over, an ultimate divestment of the mega-financial service mergers currently allowed.

III. ANTITRUST LAW IS APPLICABLE TO THE BANKING AND FINANCIAL SERVICES INDUSTRIES

Economic policies[19] certainly reflect and enforce community standards, particularly freedom to compete, and these economic policies are, in part, carried out through antitrust law. However, as with many of our community standards reflected in laws, the standard is not categorical; rather it is hypothetical. Specifically, the financial services and banking sector of the

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see also Jack N. Rakove, *Confessions of an Ambivalent Originalist*, 78 N.Y.U. L. REV. 1346, 1350-51 (2003).

[15] Rakove, *supra* note 14, at 1350-51.

[16] Peterson, *supra* note 14, at 260.

[17] Rakove, *supra* note 14, at 1350-51.

[18] Peterson, *supra* note 14, at 260-61; Wong, *supra* note 13, at 412.

[19] Economic Policy is defined as "the views, resolutions, regular decisions, acts of state, which it applies for influencing the economy to achieve its social-political goals." Gábor Sághi, *What is Economic Policy For?*, 10 PERIODICA POLYTECHNICA SER. SOC. MAN. SCI. 191, 191-92 (2002) (citing GAZDASÁGPOLITIKA (ECONOMIC POLICY) 17 (J. Veress ed., 1999)), *available at* http://www.pp.bme.hu/so/2002_2/pdf/so2002_2_01.pdf.

economy is highly regulated, leading one to inquire whether these mergers are subject to a different set of standards or laws. Generally speaking, the answer is no. That said, courts have identified certain issues specific to bank merger cases. These issues include defining the product market based upon now repealed regulatory limits and the needs of the community defense. The problem is that changing economic realities may make the defined product market and needs of the community defense more difficult to apply. Indeed, while bank merger cases are helpful in understanding the reason for regulatory agency approval of these bank mega-mergers, we are now dealing more with conglomerates[20] of financial services, which include commercial banking, investment banking, brokerage services, merchant banking and insurance activities. As the Supreme Court has yet to rule on a beast of this nature, we are left to speculate as to the outcome of future antitrust challenges, but the bank merger cases make a good starting point.

A. The Community Standard of Freedom to Compete Reflected in Antitrust Law

Federal antitrust law reflects the United States economic policy that competition is desirable for national economic health and that unreasonable restraints on trade and monopolization, potential or actual, should be prohibited.[21] To achieve this purpose, United States antitrust law prohibits the over-concentration of private sector wealth and power.[22] This is realized through several laws, including the Clayton Act.[23] However, it is case law interpreting antitrust law that clearly

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[20] A conglomerate combination in antitrust law has been defined as a merger "in which one company in two separate industries combined with another in a third industry for the purpose of establishing a diversified line of products." United States v. Cont'l Can Co., 378 U.S. 441, 449 (1964).

[21] Jacob L. Kahn, *From* Borden *to* Billing*: Identifying a Uniform Approach to Implied Antitrust Immunity from the Supreme Court's Precedents*, 83 CHI.-KENT L. REV. 1439, 1439 (2008).

[22] Oliver Zhong, *The Failing Company Defense After the Commentary: Let it Go*, 41 U. MICH. J.L. REFORM 745, 753 (2008).

[23] 15 U.S.C. § 18 (2006) prohibits mergers that may substantially lessen competition primarily because of the resulting firm having too much market power.

reflects these community standards; for example:

> Antitrust laws in general, . . . are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms. And the freedom guaranteed each and every business, no matter how small, is the freedom to compete—to assert with vigor, imagination, devotion, and ingenuity whatever economic muscle it can muster.[24]

This economic policy favoring competition is based on more than theory; it is based on past experience. Concerns over big business shutting out small business through unfair tactics, thus reducing competition, and the ultimate effect on the consumer are the impetus behind antitrust law.[25]

B. The Normative Application of Antitrust Law in Bank Mergers

The basic antitrust enforcement mechanism relating to anticompetitive acquisitions is found in section 7 of the Clayton Act, which prohibits the acquisition of one firm by another if such an acquisition may substantially lessen competition.[26] To determine if there is a substantial lessening of competition, courts and regulatory authorities usually examine evidence of market concentration, which is determined by an evaluation of the relevant line of commerce (relevant product) and the relevant geographic market (relevant market).[27] Essentially, a substantial lessening of competition may be found if the "probable" effects of the merger tend to lead to high market

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[24] United States v. Topco Assocs., 405 U.S. 596, 610 (1972).

[25] PHILLIP AREEDA, LOUIS KAPLOW & AARON EDLIN, ANTITRUST ANALYSIS 40-42 (6th ed. 2004).

[26] 15 U.S.C § 18.

[27] *See* United States v. Phila. Nat'l Bank, 374 U.S. 321, 355-56 (1963); Merger Guidelines, *supra* note 9, at § 1;R. Alton Gilbert & Adam M. Zaretsky, *Banking Antitrust: Are the Assumptions Still Valid?*, FED RES. BANK OF ST. LOUIS REV., Nov./Dec. 2003, at 29, 30, *available at* http://research.stlouisfed.org/publications/review/03/11/gilbert.pdf; Katerina Simons & Joanna Stavins, *Has Antitrust Policy in Banking Become Obsolete?*, NEW ENG. ECON. REV., Mar./Apr. 1998, at 13, 14, *available at* http://www.bos.frb.org/economic/neer/neer1998/neer298b.pdf.

concentration or power in the hands of few firms.[28]

Generally speaking, antitrust law is applicable across industry sectors unless there is express or implied immunity.[29] There is no immunity for banking or financial services, so courts are to apply the standard antitrust analysis with a few variations.[30] For example, the banking industry is, to some extent, a regulated industry. Accordingly, the Federal Reserve, Comptroller of the Currency, Federal Deposit Insurance Corporation (regulatory) and Department of Justice (law enforcement) share banking antitrust enforcement.[31] Any proposed merger must be approved by the proper regulatory agency, but even if an agency grants approval the Department of Justice can challenge the merger.[32] In such a case, the Department of Justice must sue within thirty days[33] of the regulatory agency reporting or approving the merger, or the merger cannot be attacked. However, the merger may still be attacked for possible antitrust violations under the Sherman Act.[34]

C. Applying the Clayton Act to Bank Mergers

The analysis to determine if a merger "substantially lessens competition" in a section 7 Clayton Act case requires evaluating market concentration of the merging entities.[35] Market

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[28] *See Phila. Nat'l Bank*, 374 U.S. at 363; Gilbert & Zaretsky, *supra* note 27, at 30.

[29] Justin Lacour, *Unclear Repugnancy: Antitrust Immunity in Securities Markets After* Credit Suisse Securities (USA) LLC v. Billing, 82 ST. JOHN'S L. REV. 1115, 1116-17 (2008).

[30] *Phila. Nat'l Bank*, 374 U.S. at 350; Carl Felsenfeld, *The Antitrust Aspects of Bank Mergers*, 13 FORDHAM J. CORP. & FIN. L. 507, 507-09 (2008); Gilbert & Zaretsky, *supra* note 27, at 29; Simons & Stavins, *supra* note 27, at 14.

[31] J. Robert Kramer II, *Antitrust Review in Banking and Defense*, 11 GEO. MASON L. REV. 111, 115 (2002); Simons & Stavins, *supra* note 27, at 14.

[32] United States v. First City Nat'l Bank, 386 U.S. 361, 368-69 (1967).

[33] *Id.* at 370. Such a time limit considering the complexity of mergers of financial services institutions, which may include banking services, seems inappropriate, especially considering the number of mergers we are witnessing in the 2008 economic crisis.

[34] 12 U.S.C. § 1828(c)(7)(C) (2006); Kramer, *supra* note 31, at 115. *See generally* 15 U.S.C. § 2 (2006) (defining Sherman Act).

[35] *Phila. Nat'l Bank*, 374 U.S. at 363.

concentration analysis takes into account the relevant product and relevant market most effected.[36] Bank merger cases have narrowly defined the relevant product as primarily commercial banking, and the relevant market as a metropolitan area served by the acquired bank.[37] However, courts are not required to be blind to changing and new economic realities.[38]

With respect to these realities, a brief history of banking regulatory law may be helpful since changes in regulatory law have brought into question the continued validity of defining the product as commercial banking and limiting the relevant market to localized banking.[39] The Great Depression raised numerous concerns regarding economic policy and its effect on financial markets.[40] Before 1933, banks could engage in many financial services transactions much as they can today.[41] This practice was curtailed due to the number of bank failures during the Great Depression and the belief that the best way to rebuild confidence in the economy was to provide more regulation of certain financial sectors, such as the banking industry.[42] Accordingly, Congress enacted the Glass-Steagall Act of 1933 which prohibited banks from conducting business in certain financial sectors.[43] Additional geographic restrictions for banks were also implemented.[44] These regulatory barriers stayed in place for many years but started to erode in the 1970's.[45] Deregulation culminated in the elimination of geographic restrictions and permission for banks to again engage in a

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[36] United States v. Marine Bancorporation, 418 U.S. 602, 618 (1974).

[37] United States v. Phillipsburg Nat'l. Bank & Trust Co., 399 U.S. 350, 359, 362-63 (1970); Wash. Mut. Savs. Bank v. FDIC, 347 F. Supp. 790, 798 (W.D. Wash. 1972).

[38] United States v. Conn. Nat'l Bank, 418 U.S. 656, 662 (1974).

[39] Timothy J. Yeager, Fred C. Yeager & Ellen Harshman, *The Financial Modernization Act: Evolution or Revolution?* 4-6 (Fed. Reserve Bank of St. Louis Superviory Policy Analysis, Working Paper No. 2004-05, 2004), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=646261.

[40] *Id.* at 4.

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.* at 5.

[45] *Id.*

myriad of financial services transactions in the name of economic efficiency.[46]

Supreme Court cases addressing the relevant product analysis regarding bank mergers predate the removal of barriers that separated commercial banking from investment banking, merchant banking, and insurance activities.[47] In defining the relevant product, the Court has applied a general "line of commerce" test, which looks at services offered and whether there are different controlling regulations.[48] For banking, the Supreme Court found in 1970 that under the economic reality of the time, the relevant product was defined primarily by commercial banking.[49] Commercial banking at the time included demand deposits, checking accounts, and trust administration.[50] That said, the Court left open the possibility that when economic realities do change, submarkets[51] may become important in situations involving the merger between a commercial bank and some other type of financial institution.[52]

The Financial Services Modernization Act allows for the

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[46] *Id.* at 5-7.

[47] *Id.* at 6. The removal of barriers between banking and other financial services came in 1999 with the Gramm-Leach-Bliley Act also known as the Financial Services Modernization Act. 12 U.S.C § 24(a) (2006). Yeager, Yeager & Harshman, *supra* note 39, at 1, 6.

[48] United States v. Phila. Nat'l Bank, 374 U.S. 321, 356 (1963).

[49] United States v. Phillipsburg Nat'l Bank & Trust Co., 399 U.S. 350, 359-63 (1970).

[50] *See id.* at 362-65.

[51] The relevant product is determined "by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes of it." Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962). Submarkets may exist within this relevant product definition. *See* United States v. E. I. du Pont de Nemours & Co., 353 U.S. 586, 593-95 (1957).

> [A] submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors. Because § 7 of the Clayton Act prohibits any merger which may substantially lessen competition "in *any* line of commerce" (emphasis supplied), it is necessary to examine the effects of a merger in each such economically significant submarket to determine if there is a reasonable probability that the merger will substantially lessen competition. If such a probability is found to exist, the merger is proscribed.

Brown Shoe Co., 370 U.S. at 325 (footnote omitted).

[52] *Phillipsburg Nat'l Bank*, 399 U.S. at 360.

comingling of many products—including commercial banking, investment banking, merchant banking, brokerage, and other securities and insurance activities—into one big financial services pot.[53] Many of the financial service corporations that are merging today with government regulatory agency approval provide credit services, banking services, investment services and insurance.[54] In short, economic realities have changed since the last Supreme Court decision on the relevant product.[55]

As for the relevant market in bank merger cases, again the economic realities have changed since the Supreme Court last addressed this issue in 1974.[56] In determining the relevant geographic area, the Court articulated a test of an area "where, within the area of competitive overlap, the effect of the merger on competition will be direct and immediate."[57] When the Supreme Court was deliberating on the relevant market to consider in a bank merger, most banking was localized in nature due to regulatory requirements.[58] Accordingly, the bank mergers in question had the most direct and immediate effect on a local rather than a statewide or nationwide level. Interstate banking became an economic reality in 1994, bringing into question what the Supreme Court would do if faced with a geographic location question today.[59] Again, the economic

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[53] Yeager, Yeager & Harshman, *supra* note 39, at 1.

[54] See websites for Countrywide Financial, http://my.countrywide.com; Merrill Lynch, http://totalmerrill.com; and Bank of America, http://bankofamerica.com (last visited Apr. 7, 2009).

[55] *See* Yeager, Yeager & Harshman, *supra* note 39, at 7.

[56] United States v. Conn. Nat'l. Bank, 418 U.S. 656, 667 (1974).

[57] *Phillipsburg Nat'l Bank*, 399 U.S. at 362. *See* BANKING STUDIES AND STRUCTURE DEPT., FED. RESERVE BANK OF KANSAS CITY, UNDERSTANDING ANTITRUST CONSIDERATIONS IN BANKING PROPOSALS 3-4, *available at* http://www.kc.frb.org/banking/references/UnderstandingAntitrusAnalysisv3.pdf (last visited Feb. 22, 2009); Gilbert & Zaretsky, *supra* note 27, at 34, 37 & 49; Simons & Stavins, *supra* note 27, at 15-16.

[58] *See, e.g.*, Bank Holding Company Act of 1956, Pub. L. No. 110-352, 70 Stat. 133 (codified at 12 U.S.C §§ 1841-49); McFadden Act, ch. 191, 44 Stat. 1224 (1927), *repealed by* Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994, Pub. L. No. 103-328, 108 Stat. 2338 (codified as amended in scattered sections of 12 U.S.C.); *see also* Yeager, Yeager & Harshman, *supra* note 39, at 5.

[59] *Phillipsburg Nat'l Bank*, 399 U.S. at 362-65. Interstate banking was started on a state-by-state basis in the 1980's and 1990's, culminating in a federal policy reflected in

realities have changed with interstate banking and particularly with internet transactions. It is doubtful that all the services provided by banks and other financial institutions are still significantly localized.

D. The Failing Company or Needs of Community Defenses

Even assuming a bank merger substantially lessens competition, the merger may be approved by the regulatory authorities or the courts under the "failing company" or "needs of community" defenses. Both defenses exonerate an otherwise illegal merger on grounds of economic efficiency.[60]

The failing company defense to a Clayton section 7 merger action requires a company asserting the defense, which is not limited to bank mergers, to establish "that its 'resources [were] so depleted and the prospect of rehabilitation so remote that it faced the grave probability of a business failure . . .' and further that it tried and failed to merge with a company other than the acquiring one."[61] It is, in essence, the "'lesser of two evils' approach."[62] This defense is reflected in the Department of Justice merger guidelines, albeit with somewhat more stringent requirements.[63]

While bank mergers require basic antitrust analysis first to determine if there is a violation of section 7 of the Clayton Act,

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the Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994.

[60] Zhong, *supra* note 22, at 745.

[61] United States v. Gen. Dynamics Corp., 415 U.S. 486, 507 (1974) (alteration in original) (citations omitted) (citing Citizen Publ'g Co. v. United States, 394 U.S. 131, 138 (1969)).

[62] *Id.*

[63] Merger Guidelines, *supra* note 9, at §5.

> A merger is not likely to create or enhance market power or facilitate its exercise if the following circumstances are met: 1) the allegedly failing firm would be unable to meet its financial obligations in the near future; 2) it would not be able to reorganize successfully under Chapter ll of the Bankruptcy Act; 3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers of acquisition of the assets of the failing firm that would both keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger; and 4) absent the acquisition, the assets of the failing firm would exit the relevant market.

Id. (footnotes omitted).

the Bank Merger Act of 1966[64] mandates regulators to also consider the "convenience and needs of the community to be served." The "convenience and needs of the community to be served" defense exonerates bank mergers which would otherwise be an antitrust violation.[65] In the banking context, Congress was concerned that a financially unsound bank might create a much greater community danger than the proposed bank merger. Accordingly, in the Bank Merger Act, Congress mandated a test that allows a smaller risk of failure to constitute a defense to a violation of section 7 of the Clayton Act when the "convenience and needs of the community to be served" requirement is sufficiently met.[66] The "convenience and needs of the community to be served" test still requires reasonable efforts to resolve the dilemma short of a merger.[67] However, it is unlikely that this test would be applicable to the non-FDIC, non-regulated aspects of the merger.[68]

In the current economic instability, situational ethics and the law seem to run a parallel course, allowing regulatory agencies to approve mergers that are otherwise in violation of antitrust laws for the greater good. Of course one might debate this greater good, questioning the gravity of the situation and whether these mergers truly help to resolve the dilemma. Indeed, the Department of Justice could still challenge these mega-bank mergers, but under the perceived economic circumstances of dire results without immediate action, such a challenge seems unlikely.

IV. So What is Going to Happen Once The Ashes Settle?

The nation's economic stability and growth depend to a

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[64] 12 U.S.C. § 1828(c)(5) (2006).

[65] United States v. Third Nat'l Bank, 390 U.S. 171, 181-82 (1968).

[66] *Id.* at 187-89; Zhong, *supra* note 22, at 760.

[67] United States v. Phillipsburg Nat'l Bank & Trust Co., 399 U.S. 350, 372 (1970) (citing *Third Nat'l Bank*, 390 U.S. at 190). *See* United States v. First City Nat'l Bank, 386 U.S. 361 (1967). *But see* Granader v. Pub. Bank, 417 F.2d 75 (6th Cir. 1969), *cert. denied*, 397 U.S. 1065 (1970) (suggesting that a failing company defense is still available in the banking sector).

[68] 12 U.S.C. § 1828(c) (2006).

significant degree on the competitive structure of the banking industry.[69] While I am reluctant at this time in history to say that anything is categorical, this much seems to be agreed upon. Granted, bank and financial service company failures undermine economic stability. Economic efficiency suggests that in such circumstances a merger makes sense and does not violate the underlying principles of antitrust laws. But we are witnessing unprecedented consolidation of our financial markets to such an extent that one wonders if Congress or the courts ever expected the failing company defense or the Bank Merger Act's "convenience and needs of community" test to exonerate such high levels of concentration.

Empirical evidence establishes that high concentration will result in low interest rates on deposits.[70] Additionally, it is likely that interest rates will increase on loans absent competition in the financial services sector. "[I]f the costs of banking services and credit are allowed to become excessive by the absence of competitive pressures, virtually all costs, in our credit economy, will be affected . . . ."[71] Thus, we may solve the acute problem of bank and financial services company failures, but suffer the chronic problem of reduced savings and increased credit costs.

No doubt, new laws and re-regulation will be implemented to address the problems faced by this economic crisis. Additionally, the big financial services companies that remain standing at the end of the day may still face antitrust problems under the Sherman Act resulting in possible divestiture. Yes, this too shall pass, but at what cost? Given the fact that much banking and financial services regulation was born out of our experience of economic crisis during the Great Depression, was it hubris for us to believe economic realities have really changed

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[69] Constance K. Robinson, Dir. of Operations, Antitrust Div., U.S. Dept. of Justice, Address Before the Association of the Bar of the City of New York: Bank Mergers-Antitrust Trends (Sept. 30, 1996), *available at* http://www.usdoj.gov/atr/public/speeches/1004.pdf.

[70] Gilbert & Zaretsky, *supra*, note 27, at 43-44; Simons & Stavins, *supra* note 27, at 21.

[71] *Phillipsburg Nat'l Bank*, 399 U.S. at 358 (citing United States v. Phila. Nat'l Bank, 374 U.S. 321, 372 (1963)).

that much? Mark Twain was right: "History doesn't repeat itself, but it does rhyme."[72]

[72] *See* The Volokh Conspiracy, *History Doesn't Repeat Itself, But it Rhymes*, http://volokh.com/archives/archive_2005_02_13-2005_02_19.shtml (last visited Feb. 22, 2009).

FAMILIES REDEFINED: KINSHIP GROUPS THAT DESERVE BENEFITS

*Jane E. Cross, Nan Palmer, and Charlene L. Smith**

ABSTRACT

In *Families Redefined: Kinship Groups that Deserve Benefits*, the authors examine 1) the nature of kinship families, 2) the benefits accorded to married couples, 3) kinship families that lack protection and benefits, 4) the impact of denying kinship families protection and benefits, 5) the use of contract law in kinship relationships, and 6) using legislation to benefit kinship relationships.

This exploration of expanding family law protections to kinship groups addresses a series of interrelated topics. The first two sections of the article explore the characteristics and creation of kinship families in different societies. The third section addresses the legal benefits provided by marriage, while

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the fourth and fifth sections examine, respectively, the types of kinship relationships that should have similar benefits and the effect of denying such benefits. The next two sections present legal solutions that propose using contract law and adopting legislation to provide legal protection and benefits to kinship units.

Accordingly, the article advocates for the expansion of legal concepts of family to include kinship relationships by comparing the treatment of these issues in various states and nations. In this manner, the authors support a new definition of family that goes beyond conjugal arrangements.

I. INTRODUCTION

As noted authorities point out, "[f]amilies are charged with the pivotal tasks of raising children and providing members with ongoing intimacy, affection, and companionship."[1] Beyond these biological and affectional attributes, the critical need for the family's economic survival exists from one generation to the next. The United States fails to fulfill those obligations of extending economic and social support to kinship families who provide love, care and socialization to others within their group. Our article offers possible solutions by redefining what constitutes a family unit. We are acutely aware that a divide exists between those who are alarmed by the idea that the state would have to legally recognize a more inclusive definition of what constitutes a kinship family and those who are indifferent. However, to ignore the facts not only punishes both children and adults who would flourish if such groups gained legitimacy, it also puts our greater social system at peril by marginalizing millions of kinship family units through restrictive laws and policies. We highlight how many such kinship families exist, what benefits they do not receive, and how that negatively impacts them from a psychosocial, health and economic perspective. Then, we briefly explore the many proposed solutions and offer some examples of what models can be used to

[1] MARY ANN LAMANNA & AGNES RIEDMANN, MARRIAGES AND FAMILIES: MAKING CHOICES IN A DIVERSE SOCIETY 8 (10th ed. 2009).

address the problem.

II. KINSHIP FAMILIES: HOW THE PAST INFORMS THE PRESENT

Kinship families, the focus of this article, have the following characteristics: the group has common goals and share concern for each other, the individuals that comprise the group usually are "'like-minded"' adults, sometimes with children, and the individuals respond to biological, emotional, spiritual, and economic needs of the group and, to the extent possible, self care. Most frequently the members of the group focus on extending love and care to the other members. Kinship families provide a continuity and coherency of life through day-to-day interactions, which is essential to human well being.[2] The term "kinship" is historically and currently defined as a "set of practices that establishes the dominance of . . . blood and legal ties over others."[3] This definition reflects a prevailing heteronormative view that gives primacy to the heterosexual relationship.[4] Kaja Finkler, a scholar in this area, points out that having biological relationships as the "starting point" for defining family relations has been called into question and argues as others have, such as pioneer David Schneider, that "kinship" narrowly defined is a Western construct.[5] Finkler takes a more generous view of kinship families, calling such units a "'significant same' group . . . who perceive themselves as similar and who consider themselves related on grounds of shared material, be it land, blood, food, saliva, semen, or ideological or affective content."[6] The continual pressure to maintain a narrow construct of kinship is evidenced by the descriptive words "fictive kin," which are frequently used by social science researchers and writers to describe arrangements

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[2] *See generally* Stephen Hicks, *Genealogy's Desire: Practices of Kinship Amongst Lesbian and Gay Foster-Carers and Adopters*, 36 BRIT. J. SOC. WORK 761 (2006).

[3] *Id.* at 763.

[4] *Id.*

[5] Kaja Finkler, *The Kin in the Gene: The Medicalization of Family and Kinship in American Society*, 42 CURRENT ANTHROPOLOGY 235, 235-36 (2001).

[6] *Id.* at 236.

that go outside the legal and genetic norms.[7] Such a position fails to continue essential connections with our past which can reveal avenues that have been used for survival and thriving. Ample support exists for a more generous and altruistic perspective that the authors of this article have taken. The past informs the present as seen in the following illustrative examples.

Exploration of our biological and social past reveals a far more integrative view of family relationships throughout the world than current Western constructs. Survival depends in significant part on the altruistic behavior of others. A society or group cannot manage all the tasks of physical, economic and emotional living without cooperation from each other. In fact, humans are biologically wired for attachment to each other as a matter of survival. Currently, scientists can trace characteristics of caring for others for both daily and generational survival through our ancestry and connection to other primates.[8] An illustrative primate connection is the bonobo, which are "female-centered [and] egalitarian," according to Frans de Waal of Yerkes Regional Primate Research Center in Atlanta and professor of psychology at Emory University.[9] Other examples may be drawn from our human ancestors. In ancient Sparta, females enjoyed many freedoms afforded to males.[10] In Sparta, girls received public education, engaged in sports, and Spartan wives could inherit and transfer wealth as

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[7] Hicks, *supra* note 2, at 762; *see also* Richard A. Wagner, *Fictive Kinship*, *in* MARRIAGE AND FAMILY ENCYCLOPEDIA (1995), http://family.jrank.org/pages/630/Fictive-Kinship.html [hereinafter *Fictive Kinship*]; MICHAEL DEAN MURPHY, A KINSHIP GLOSSARY: SYMBOLS, TERMS, AND CONCEPTS (2001), http://www.as.ua.edu/ant/Faculty/murphy/436/kinship.htm.

[8] Anthony DeBartolo, *The Bonobo: "Newest" Apes are Teaching Us About Ourselves*, CHI. TRIB., June 11, 1998, at TEMPO1, *available at* http://www.hydeparkmedia.com/bonobo.html. According to DeBartolo, "[t]he bonobo's apparent ability to empathize, in contrast with the more hostile and aggressive bearing of the related chimpanzee, has some social scientists re-thinking our behavioral heritage . . . ." *Id.*

[9] *Id.*

[10] *See* Helena P. Schrader, *Sparta Reconsidered: Spartan Women*, http://elysiumgates.com/~helena/Women.html (last visited Apr. 23, 2009).

well as control and manage land.[11] "The freedom and greater respect for Spartan women began at birth with laws that required female infants and children to be given the same care and food as their brothers . . . ."[12]

In North America "traditional tribal lifestyles are more often gynocratic than not, and they are never patriarchal."[13] Their lifestyles exhibit a generous array of human expression not confined to the Puritanical notions instituted by Anglo Europeans.[14]

> In tribal gynocratic systems a multitude of personality and character types can function positively within the social order because the systems are focused on social responsibility rather than on privilege and on the realities of the human constitution rather than on denial-based social fictions to which human beings are compelled to conform by powerful individuals within the society.[15]

As to the sexual roles of Native American/First Nations peoples, "two-spirit people" were valued because it was believed that they could understand the perspectives of both males and females.[16] Among the American Plains Indians, such multi-spirit people are often referred to by others as Berdache; a man might assume both the dress and role of a woman, and he might marry another man.[17] "Rather than being viewed as an

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[11] *Id.*

[12] *Id.* An example from another continent is present in Africa. "Among the many myths Europeans have created about Africa, the myth that homosexuality is absent or incidental in African societies is one of the oldest and most enduring." *Preface to* BOY-WIVES AND FEMALE HUSBANDS: STUDIES IN AFRICAN HOMOSEXUALITIES, at xi (Stephen O. Murray & Will Roscoe eds., 1998). A central theme in this work is the impact of Western morality and ethnocentrism on what might be called "discovered populations." In other words, forms of social arrangement and gender expression were "closeted" in the writings of early explorers. *See id.* at 12.

[13] PAULA GUNN ALLEN, THE SACRED HOOP: RECOVERING THE FEMININE IN AMERICAN INDIAN TRADITIONS 2 (1986).

[14] *Id.*

[15] *Id.* at 3.

[16] *A Native American Perspective on the Theory of Gender Continuum*, http://concernedcounseling.com/communities/Gender/intersexuals/article_native_american.htm (last visited Mar. 16, 2009) [hereinafter *Native American Perspective*].

[17] *Id.* "Some Native Americans object to the very word used to describe the special

aberration, the role was seen as one, which bridged the gap between the temporal and the spirit worlds."[18] This spiritual aspect "was emphasized far more than the homosexual or gender variant aspect." For this reason, "berdaches were highly valued by the people of the tribe."[19] According to the writings of Edwin T. Denig, who lived for decades among First Nations peoples as a trader for the American Fur Company, "among the Crows, men who dressed as women and specialized in women's work were accepted and sometimes honored."[20] Denig also wrote of women who were warriors leading men into battle and of women who had multiple wives. "Instead of hypermasculine braves and submissive squaws we find personalities of surprising diversity and complexity."[21] Another example is Potlatch, a system of gift giving used by Canada's Kwakiutl Indians as a way of ensuring that they can rely on each other. In this cultural practice, gifts such as blankets and specially made copper pieces are currency. Gray summed it up most eloquently, "Only giving and receiving that is completely unencumbered reflects the true grace of generosity. Everything else is a deal."[22] In this manner, help is assured among all people through a social structure that promotes mutual cooperation.[23]

Another illustrative example of the fluidness of family and how it successfully functions is the concept of godparenthood, or compadrazgo, as it occurs in Mexico and Latin America.[24] This

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role of berdache. Some sources say the term [berdache] has its origins in an Arab word for male prostitute or 'kept' boy and was coined not by the Indians, but by Europeans." *Id.* "Berdache" is a term most often used by anthropologists but is now out of favor by many Native Americans. *See* WILL ROSCOE, CHANGING ONES: THIRD AND FOURTH GENDERS IN NATIVE NORTH AMERICA 7, 17-19 (1998); *see also* Wesley Thomas & Sue-Ellen Jacobs, "... *And We Are Still Here*": *From Berdache to Two-Spirit People*, 23 AM. INDIAN CULTURE & RES. J. 91-92 (1999).

[18] *Native American Perspective*, *supra* note 16.

[19] *Id.*

[20] ROSCOE, *supra* note 17, at 3.

[21] *Id.* at 4.

[22] Sharon Gray, *The Power in Giving Presents*, AGE, Oct. 16, 2007, at Metro14.

[23] *Fictive Kinship*, *supra* note 7.

[24] Shawn Malia Kana'Iaupuni et al., *Counting on Kin: Social Networks, Social Support, and Child Health Status* 83 SOC. FORCES 1137, 1140-41 (2005).

well-documented practice names persons frequently not related by blood or marriage as protectors of newborns and others who are passing through important life events and carries with it rights and obligations for a life time.[25] Accompanying this practice is that of confianza, a presence of trust necessary for reciprocal exchange.[26] "How the family organizes itself, how it retains its cohesion, how openly it communicates and problem-solves together to cope with threat, largely forecasts its ability to recover, evolve, and adapt over time."[27]

While each of these examples has limitations so far as exemplifying totally egalitarian cultures, they do present a range of options and creative solutions to division and discrimination. Given a more generous and inclusive definition, kinship families can include grandparents caring for their grandchildren, single mothers, daughters or sons caring for their parents, friends caring for friends[28] and, of course, same-sex couples caring for each other and any children they may have.[29]

III. WHAT BENEFITS DO OPPOSITE SEX 'MARRIED' COUPLES, EVEN WITHOUT CHILDREN, RECEIVE?

According to the United States Government Accountability Office (GAO), over a thousand federal laws treat married people differently from so-called "single" people.[30] Numerous benefits

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[25] *Id.*

[26] *Id.*

[27] IRENE GOLDENBERG & HERBERT GOLDENBERG, FAMILY THERAPY: AN OVERVIEW 8 (5th ed. 2000).

[28] *See* Laura A. Rosenbury, *Friends With Benefits?*, 106 MICH. L. REV. 189, 221-26 (2007). In her very insightful article, Professor Rosenbury advocates extending rights to friends. *Id.* at 236. She notes that such an extension would "signal that marriage need not be the only site for emotional care and support." *Id.* at 240.

[29] *See generally* Katherine Acey et al., Beyond Same-Sex Marriage: A New Strategic Vision for All Our Families & Relationships, http://beyondmarriage.org/BeyondMarriage.pdf. Beyondmarriage.org advocates expansion of who should receive "marriage benefits" through "legal recognition for a wide range of relationships, households and families . . . ." *Id.* at 5. Upon examination, it is noticeable that the list they would extend this legal recognition to mirrors ours. *See infra* note 41.

[30] Letter from Dayna K. Shah, Associate General Counsel, United States General Accounting Office, to The Honorable Bill Frist, Former Majority Leader, United States

are automatically granted upon those who are married, which include employee-sponsored health benefits, spousal medical decision-making, family visitation rights for spouses, next-of-kin status for emergency medical decisions or filing wrongful death claims, funeral and bereavement leave, permission to make funeral arrangements for a deceased spouse, joint adoption and foster care, joint parenting rights, such as access to children's school records, access to "family only" services, such as reduced membership to clubs or residency in certain neighborhoods, insurance coverage, joint tax filing and joint filing of bankruptcy.[31]

If one spouse dies, benefits accrue to the surviving spouse. For example, the surviving spouse may receive social security pensions, veteran's pensions, educational assistance, continuation of employer-sponsored health benefits, supplemental security income, income tax deductions, Medicaid disbursements, property tax exemptions, the right to inherit property, and spousal privilege in court.[32] Of course, there are also the rights that continue despite the fact that the marriage has ended in divorce. These rights are custodial rights to

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Senate (Jan. 23, 2004) (on file with the United States General Accounting Office), *available at* http://www.gao.gov/new.items/d04353r.pdf. The Office of General Accounting listed thirteen categories of federal laws affected by marital status. *Id.* at 2. These categories include the following: "Social Security and Related Programs, Housing, and Food Stamps," "Veterans' Benefits," "Taxation," "Federal Civilian and Military Service Benefits," "Employment Benefits and Related Statutory Provisions," "Immigration, Naturalization, and Aliens," "Indians," "Trade, Commerce, and Intellectual Property," "Financial Disclosure and Conflict of Interest," "Crimes and Family Violence," "Loans, Guarantees, and Payments in Agriculture," "Federal Natural Resources and Related Statutory Provisions," and "Miscellaneous Statutory Provisions." *Id.* at 3-10.

[31] *Id.* According to the letter there are "1,138 federal statutory provisions classified to the United States Code in which marital status is a factor in determining or receiving benefits, rights, and privileges." *Id.* at 1. These include: "exclusion of certain individuals and entities from participation in Medicare and state health care programs," "eligibility under first-time home-buyer programs," and "medical care for survivors and dependents of certain veterans." *Id.* at 3-4.

[32] It must be noted that "[i]n recent years, couples in which both partners have similar incomes generally pay a marriage tax, while couples in which only one individual works receives a marriage subsidy." James Alm & Leslie A. Whittington, *For Love or Money? The Impact of Income Taxes on Marriage*, 66 ECONOMICA 297, 300 (1999). This is commonly known as the marriage penalty.

children, shared property, child support and alimony, to name just a few.[33]

IV. How Many Kinship Families Go Without the Benefits? Why Should We Be Concerned?

Through the inter-relationship of our biology, our social environment, and our psychological attributes, we can examine how social and economic injustice is detrimental to all humans. Our survival as a species depends on this. Why should we be concerned about the detrimental impact for all human beings? First, regardless of the differences between those who have power and those who do not, we all have in common the biology of humanness. This biology of humans is often distinguished from other species through the attributes of the human brain.

> It is the brain that allows us to be connected to each other in the present. . . . [I]t is the brain that connects us to the future as we pass elements of our life experience to the next generations. It is the brain that allowed humankind to create humanity.[34]

For example, while our human expression is multifaceted, we all have in common our neurobiological need for attachment or, as Virginia Satir called it, "making contact."[35] Attachment is

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[33] The common law presumption that a mother should have custody of minor children is an unconstitutional discrimination against fathers, depriving them of their right to equal protection under the Fourteenth Amendment. State *ex rel.* Watts v. Watts, 350 N.Y.S.2d 285, 291 (N.Y. Fam. Ct. 1973). Not including separate property acquired before marriage, the court in a divorce case may, without regard to title, exercise broad discretion in distributing all other property accumulated during marriage. Darling v. Darling, 444 A.2d 20, 23 (D.C. 1982). Child support is an obligation imposed by one parent on the other for the benefit of the child, not for the benefit of the other adult. Barnett v. Barnett, 802 So. 2d 1203, 1204 (Fla. Dist. Ct. App. 2002). It is a dual obligation owed by both biological parents to their child that begins at the child's birth. *Id.* Alimony is provided either for permanent or rehabilitative support, or as assistance in the equitable distribution of marital property. Martin v. Martin, 582 So. 2d 784, 786 (Fla. Dist. Ct. App. 1991). When considering alimony, gender is irrelevant. Heath v. Heath, 611 So. 2d 1249 (Fla. Dist. Ct. App. 1993).

[34] Bruce D. Perry, Brain Structure and Function I: Basics of Organization 2 (2002), http://www.childtrauma.org/CTAMATERIALS/brain1_inter_02.pdf.

[35] *See generally* Virginia Satir, Making Contact (1976).

biologically driven and influenced by the human brain.[36] Attachment affords us safety and protection against the challenges of living and is present in other mammalian life.[37] The persistence of social, political, and legal systems to demand and subsequently reflect the restrictive definition of family and kinship family has damaging consequences for families of today. Oppression of all kinds carries with it immense protracted psychological trauma and, for many, physical trauma as well. "Traumatic events are extraordinary, not because they occur rarely, but rather because they overwhelm the ordinary human adaptations to life."[38] In recent years, the term "historical trauma" has emerged to recognize the "associated bereavement" and "unresolved grief" and its transfer through generations.[39] "This grief may be considered impaired, delayed, fixated, and/or disenfranchised."[40] The following sections discuss examples of kinship families struggling to not only survive, but to thrive amidst the constant challenges of discrimination, oppression, and disenfranchisement.[41]

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[36] JON G. ALLEN, COPING WITH TRAUMA: A GUIDE TO SELF-UNDERSTANDING 37 (1995).

[37] *Id.* at 302.

[38] JUDITH LEWIS HERMAN, TRAUMA AND RECOVERY 33 (1997).

[39] Maria Yellow Horse Brave Heart, *The Impact of Historical Trauma: The Example of the Native Community*, *in* TRAUMA TRANSFORMED: AN EMPOWERMENT RESPONSE 176, 178 (Marian Bussey & Judith Bula Wise eds., 2007).

[40] *Id.*

[41] *See* Acey et al., *supra* note 29, at 2. Most of the following types of kinship households identified by Acey would include related individuals:

- Senior citizens living together, serving as each other's caregivers, partners, and/or constructed families
- Adult children living with and caring for their parents
- Grandparents and other family members raising their children's and/or a relative's children
- Committed, loving households in which there is more than one conjugal partner
- Blended families
- Single parent households
- Extended families (especially in particular immigrant populations) living under one roof, whose members care for one another
- Queer couples who decide to jointly create and raise a child with another queer person or couple, in two households
- Close friends and siblings who live together in long-term, committed, non-

A. Grandparents Raising Their Grandchildren

Millions of grandparents in the United States currently raise their grandchildren.[42] According to the 2000 census, 2.4 million grandparents are responsible for their grandchildren who live with them.[43]When grandparents were the head of household, the average family income for 1996 was between $19,750 and $61,632.[44] Further, 2.4 million children live in households where the grandparents take primary responsibility for the children's needs.[45] Specifically, in Kansas, 29,026 grandchildren under the age of eighteen live in a grandparent-headed household.[46] Of these households, 13.2% live in poverty.[47] In one Wisconsin county, 14% of the children are being raised by grandparents.[48]

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conjugal relationships, serving as each other's primary support and caregivers

- Care-giving and partnership relationships that have been developed to provide support systems to those living with HIV/AIDS.

Id.

[42] AARP, Census 2000 Data about Grandparent-Headed Households, http://www.aarp.org/families/grandparents/grandparents_resources/a2004-01-16-census2000data.html (last visited Sept. 28, 2008).

[43] TAVIA SIMMONS & JANE LAWLER DYE, GRANDPARENTS LIVING WITH GRANDCHILDREN: 2000 (Oct. 2003), http://www.census.gov/prod/2003pubs/c2kbr-31.pdf. "The number of *households* with coresident grandparents is different from the number of *people* who are coresident grandparents. In 2000, 4.1 million households included coresident grandparents, but these households contained 5.8 million coresident grandparents." *Id.* at 9.

[44] Age Venture News Service, *National Grandparent Daze Seems Inevitable*, Sept. 25, 1998, http://www.demko.com/m980921.htm.

[45] SIMMONS & DYE, *supra* note 43, at 1; *see also* Children's Bureau Express, Online Support for Grandparents Raising Grandchildren, http://cbexpress.acf.hhs.gov/index.cfm?issueId=23 (follow "Online Support for Grandparents Raising Grandchildren" hyperlink under "Resources") (last visited Apr. 10, 2009). "Nationally, there are 5.4 million children living in homes headed by a relative other than a parent. Thirty-nine percent □ 2.1 million of these children □ are being raised solely by grandparents or other relatives *with no parents present* in the household." MARY K. BISSELL & MARYLEE ALLEN, HEALTHY TIES: ENSURING HEALTH COVERAGE FOR CHILDREN RAISED BY GRANDPARENTS AND OTHER RELATIVES 115 (2001), http://cdf.convio.net/site/DocServer/healthyties_fullreport.pdf?docID=638.

[46] AARP FOUNDATION, GRANDFACTS: A STATE FACT SHEET FOR GRANDPARENTS AND OTHER RELATIVES RAISING CHILDREN 1 (Oct. 2007), http://www.grandfactsheets.org/doc/Kansas%2007.pdf.

[47] *Id.*

[48] Mary Crave, Wisconsin Children Living in Households Headed by a Grandparent

Studies demonstrate that when grandmothers are the head of household the children suffer the most because no one else shares the burden of raising the children, and grandmothers as a group, because of their age and sex, are relatively unlikely to be economically independent.[49] A study by the Urban Institute concluded that 37% of the grandparents raising grandchildren had incomes below the national poverty level.[50] Since many of these grandparents heading households do not have formal custody of the children, it frequently becomes a very difficult problem to receive health care or put them in a local school.[51] Further, grandfathers when specifically studied showed even greater marked distress, in that they tended to be older than grandmothers when they started caring for their grandchildren, were in poorer health, and experienced greater emotional strain.[52] An example of the impact of discrimination is found in Native American grandparents raising their grandchildren, as "there is a generation of Native Americans who do not feel a sense of competency or efficacy in their parenting abilities because they were not reared by their biological parents and were not taught the traditional ways of their culture and families of origin" and as such, "[t]he historical trauma associated with cultural genocide and boarding schools likely remain in the psyches of many Native American people, impacting their psychological well-being."[53]

— 1990 (Nov. 1990), http://www.uwex.edu/ces/gprg/wisite.pdf.

[49] Lynne M. Casper & Kenneth R. Bryson, *Co-resident Grandparents and Their Grandchildren: Grandparent Maintained Families*, (U.S. Census Bureau Population Division, Working Paper No. 26, 1991), *available at* http://www.census.gov/population/www/documentation/twps0026/twps0026.html.

[50] *Skipping a Generation: Grandparents Raising Grandchildren*, ECONOMIST, June 16, 2007, at 39.

[51] *Id.*

[52] Janet Okagbue-Reaves, *Kinship Care: Analysis of the Health and Well-Being of Grandfathers Raising Grandchildren Using the Grandparent Assessment Tool and the Medical Outcomes Trust SF-36 TM Health Survey*, 9 J. FAM. SOC. WORK 47, 64 (2005).

[53] Sandra Bailey & Bethany Letiecq, *The Mental Health of Rural Grandparents Rearing Their Grandchildren*, 22 FOCAL POINT 24 (2008), *available at* http://www.rtc.pdx.edu/PDF/fpS0808.pdf; *see* Kathleen Graves et al., Boarding School Project: Mental Health Outcome, pp. ii, 1-5 (July 2007), http://elders.uaa.alaska.edu/reports/other_boarding-school-project.pdf; *see also* Carolyn

B. Same-Sex Kinship Families

The number of same-sex couples has quintupled since 1990 according to census data.[54] The growth in same-sex couples was proportionally twenty-one times larger than the general population growth from 1990 to 2006.[55]

Comparing various state statistics gives a broad perspective of what impact the lack of resources has upon the groups. For instance, census data shows that 17% of same-sex couples in Florida are raising children.[56] However, according to the Williams Institute Fellows, "same-sex parents have fewer economic resources to provide for their families than do their married counterparts: they have lower household incomes and lower rates of home ownership."[57] Kansas mirrors Florida in many ways, where 17% of Kansas same-sex couples are also raising children under the age of eighteen.[58] Further, in both

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Barcus, *Recommendations for the Treatment of American Indian Populations*, *in* PSYCHOLOGICAL TREATMENT OF ETHNIC MINORITY POPULATIONS, (Council of Nat'l Psychol. Ass'ns for the Advancement of Ethnic Minority Interests), Nov. 2003, at 27, *available at* http://www.apa.org/pi/oema/programs/empa_ptemp.pdf.

[54] Gary J. Gates, Geographic Trends Among Same-Sex Couples in the U.S. Census and the American Community Survey 1 (Nov. 2007), http://www.law.ucla.edu/williamsinstitute/publications/ACSBriefFinal.pdf. Of course, some of the "growth" can be attributed to the willingness of those in a partnership to "come out." *Id.* at 1-2; *see also* 2000 Census Information on Gay And Lesbian Couples, by State, http://www.gaydemographics.org/USA/2000Census_Gay_state.htm (last visited Oct. 2, 2008).

[55] Gates, *supra* note 54, at 1. The U.S. Census Bureau admits that the "same-sex spouse" responses were "flagged as invalid" because such a response was contrary to the 1996 Federal Defense of Marriage Act. U.S. Census Bureau, Technical Note on Same-Sex Unmarried Partner Data from the 1990 and 2000 Censuses, http://www.census.gov/population/www/cen2000/samesex.html (last visited June 19, 2008). Thus, the "real" numbers are still suspect. *Id.*

[56] Adam P. Romero et al., The Williams Institute, Census Snapshot: Florida 1 (Dec. 2007), http://www.law.ucla.edu/williamsinstitute/publications/FloridaCensusSnapshot.pdf [hereinafter Florida Snapshot].

[57] *Id.* "While 49% of same-sex couples with children own their home, a much larger percentage of married parents (77%) own their home." *Id.* at 3.

[58] *Id.*; Adam P. Romero et al., The Williams Institute, Census Snapshot: Kansas 2 (Jan. 2008), http://www.law.ucla.edu/williamsinstitute/publications/KansasCensusSnapshot.pdf [hereinafter Kansas Snapshot].

Florida and Kansas, "same-sex parents have far fewer financial resources to support their children than married parents."[59] In Kansas, "[t]he median household income of same-sex couples with children is $50,400, or 11% lower than that of married parents ($56,530)."[60] In Florida, "[t]he median household income of same-sex couples with children is $43,000, or 23% lower than that of married parents ($55,500)."[61]

C. Cohabitating Kinship Families

Two prominent examples of cohabitating kinship are senior citizens living together without marrying and opposite-sex couples who have decided not to marry.

According to the AARP, there are 266,600 seniors (sixty-five years and above) who live together without being married.[62] These figures might be very low in comparison to actual numbers for a variety of social reasons; most importantly, seniors may be reluctant to admit they cohabitate.[63] Further, as the AARP points out, this group is expected to have a sudden growth spurt with the onset of the "baby boomers" reaching retirement age.[64]

Regarding non-seniors, according to a survey, younger couples are "more than twice as likely" to live together before marriage as older couples.[65] The survey showed that 40% of all U.S. adults say they have lived with a romantic partner without going through a marriage ceremony.[66] That is, 9.7 million Americans reported living with opposite-sex partners in 2000.[67]

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[60]Kansas Snapshot, *supra* note 58, at 3; [F]lorida Snapshot, *supra* note 56, at 3.

[60] Kansas Snapshot, *supra* note 58, at 3.

[61] Florida Snapshot, *supra* note 56, at 3.

[62] Linda Greider, *Unmarried Together*, AARP BULL. TODAY, Oct. 8, 2004, http://www.aarp.org/family/articles/shacking.html.

[63] *Id.*

[64] *Id.*

[65] *New Legal Concerns for Cohabitating Couples*, LAWYERS.COM, July 19, 2005, http://research.lawyers.com/New-Legal-Concerns-for-Cohabitating-Couples.html (survey commissioned by LexisNexis and Martindale-Hubbell).

[66] *Id.*

[67] Alternatives to Marriage Project, http://www.unmarried.org/statistics.html (last visited Apr. 20, 2009).

This was a 72% increase between 1990 and 2000.[68] Further, in 2006, 40% of all babies were born out of wedlock.[69] In comparison, only 18% of babies were born outside of marriage in 1980.[70] Some of this increase is attributed to the growing fear of thirty-plus year-old single women that they will not be able to have a child.[71] Women worry more about marrying the "'wrong" man than having a child out of wedlock.[72] Even though older single women are having more babies out of wedlock, it is teenagers who have the most with "[m]ore than 80% of babies delivered by teen mothers . . . born out of wedlock."[73]

D. Kinship Families That Are Largely Focused on Caregiving

These particular groups can include a fairly broad spectrum of people, from senior citizens living together, to extended or blended families that frequently typify the immigrant community, to caregivers such as sons and daughters caring for their elderly parents, to single moms, or to a caregiver who is looking after an AIDs stricken friend.

> More than 50 million Americans care for a family member or friend with a chronic illness, disability or advanced age during any given year, according to a 2000 survey by the National Family Caregivers Association. And the number of people who take on this role will likely boom: The proportion of the U.S. population who are adults 65 and older will rise from 12 to 17 percent in the next 20 years, according to the U.S. Census Bureau.[74]

Health care costs partially explain why children are taking care of their parents. Seniors find themselves financially strapped and often turn to their children to help them out. The

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[68] *Id.*

[69] Rochelle Sharpe, *Out-of-Wedlock Births*, USA WEEKEND, Feb. 17, 2008, http://www.usaweekend.com/08_issues/080217/080217by-numbers.html.

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] *Id.*

[74] Zak Stambor, *Caring for Caregivers*, 37 MONITOR ON PSYCHOL. 46, 46 (Nov. 2006), *available at* http://www.apa.org/monitor/nov06/caregivers.html.

children, otherwise known as the "'sandwich" generation, find themselves caring for both their parents and their own children.[75] "Women represent more than two-thirds of adults providing substantial assistance to elderly parents."[76] According to a report, these women "provide an annual average of $1,521 in financial support to elderly parents and spend 23 hours a week (1,210 hours a year) on average providing care to elderly parents."[77]

Regarding extended families, even the Census Bureau is cognizant of the fact that "'families" in America have become very complex. In 2000, the Bureau added categories such as adopted child, step child, foster child, grandchild, parent-in-law, son/daughter-in-law, brother/sister-in-law, nephew/niece, grandparent, uncle/aunt, cousins and un-married partner to the relationship items on who is considered a part of the household.[78] There were seventy-nine million "Family Groups" in 2003 where at least one subgroup lived in the household.[79] For example, if a daughter lives with her parents and she has a child who also lives there, the mother and child are considered a subgroup.[80] Of U.S. states, Hawaii has the highest percentage of multigenerational family households, with 8.2%, closely followed by California (5.6%) and Mississippi (5.2%).[81] About 2% of the identified multigenerational families' households consist

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[75] JOINT ECONOMIC COMMITTEE, FACT SHEET: INVESTING IN FAMILIES TAKING CARE OF ELDERLY PARENTS 1 (Feb. 2007), *available at* http://jec.senate.gov/archive/Documents/Reports/investinginfamiliestakingcareofelderlyparents.pdf [hereinafter INVESTING IN FAMILIES].

[76] *Id.* (citing RICHARD W. JOHNSON & JOSHUA M. WIENER, A PROFILE OF FRAIL OLDER AMERICANS AND THEIR CAREGIVERS 64 tbl. 5.4 (Feb. 2006), http://www.urban.org/UploadedPDF/311284_older_americans.pdf).

[77] *Id.* (citing Charles R. Pierret, *The 'Sandwich Generation': Women Caring for Parents And Children*, MONTHLY LAB. REV., Sept. 2006, at 8 tbl. 7, *available at* http://www.bls.gov/opub/mlr/2006/09/art1full.pdf).

[78] TAVIA SIMMONS & GRACE O'NEILL, U.S. CENSUS BUREAU, HOUSEHOLDS AND FAMILIES: 2000, 1 (Sept. 2001), http://www.census.gov/prod/2001pubs/c2kbr01-8.pdf.

[79] JASON FIELDS, U.S. CENSUS BUREAU, AMERICA'S FAMILIES AND LIVING ARRANGEMENTS: 2003 6 (Nov. 2004), http://www.census.gov/prod/2004pubs/p20-553.pdf.

[80] *Id.*

[81] SIMMONS & O'NEILL, note 78, at 7.

of three generations.[82]

V. What Is the Impact on Kinship Families When Benefits Are Denied?

The family constellation has dramatically shifted from the American ideals portrayed in the media during the 1950s. However, the legal structure has continued to stigmatize and censure those who deviate from the ideal form of "husband, wife, and children in an independent household—the nuclear family model."[83] The persistence of social, political, and legal systems to demand and subsequently reflect this antiquated ideal has damaging consequences for families of today. From an ecological perspective—that is, taking the view that people and families are influenced both positively and negatively by the context in which they live—"many causes of family stress originate outside the family," such as social and legal structures and neighborhoods or communities.[84] Policies may deeply constrain or benefit a family depending on how closely it fits the ideal.[85]

The infrastructure of any society (in the U.S. for example: white, male, and moneyed) controls who is allowed "to move upward" and who is maintained in a position of powerlessness.[86] "Powerlessness . . . , the *inability* to achieve benefits for oneself. . . . [or one's family] is a very painful condition—there is a sense in which one has no control over one's life."[87] The presence of powerlessness and lack of control is described in essentially every narrative concerning trauma and both overt and covert violence.

The presence of ongoing coercive control has dramatic implications. In 1973, Amnesty International found that, whether a political prisoner or domestic partner, and

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[82] *Id.* at 8.

[83] LAMANNA & RIEDMANN, *supra* note 1, at 3.

[84] *Id.* at 391.

[85] *Id.*

[86] JULIET C. ROTHMAN, CULTURAL COMPETENCE IN PROCESS AND PRACTICE: BUILDING BRIDGES 27 (2008).

[87] *Id.* at 26.

irrespective of culture, age, or any other characteristic, "[t]he methods of establishing control over another person are based upon systematic, repetitive infliction of psychological trauma. They are the organized techniques of disempowerment and disconnection. . . . [that] destroy the victim's sense of self in relation to others."[88] Legal and social institutions that reflect the current power structure do just that. There are significant implications for both individuals and kinship families.

The social and legal environment itself may be threatening when it includes legal barriers or practices that disenfranchise a person, family, or group. In any threatening situation, the brain will respond protectively through a stress-response system.[89] The brain mediates and controls "the neuromuscular, autonomic, endocrine and immune systems."[90] Children in a state of fear retrieve information from the world differently than children who feel calm.[91] A context composed of persistent and pervasive levels of "threatfulness" impacts both the child and the family. Families, even groups, under the constant siege of a malevolent society, feel the affect of this ongoing trauma. The human species above all must physically and mentally survive in order to last into the future. Given challenges from all sides, it will take a fully cooperative and human effort to succeed. The outlook is one of uncertainty. For example, the health care system reflects the larger society and "therefore mirrors the inequalities in society."[92]

> The western health care system is a system where the majority of doctors are male, and the majority of nurses are female - again gendered on power lines; where the people of colour tend to be found either in the roles [sic] of the patients, or in the kitchens, laundries, and janitorial services of most hospitals.[93]

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[88] HERMAN, *supra* note 38, at 77.

[89] *See* PERRY, *supra* note 34, at 5.

[90] *Id.* at 7.

[91] *Id.* at 5.

[92] Yasmin Jiwani, *Changing Institutional Agendas in Health Care: Plenary Presentation at Removing Barriers: Inclusion, Diversity and Social Justice in Health Care* (May 25-27, 2000), http://www.harbour.sfu.ca/freda/articles/barrier.htm.

[93] *Id.*

Given these challenges from all sides and the continued oppressive restriction of policies and practices, Irhapeti Ramsden, a Maori nurse. and her colleagues developed a concept for assessing cultural risk.[94] The purpose of this assessment was to increase cultural safety and sensitivity practices.[95] However, Ramsden argues that the approach is only possible when cultural groups have the power within the systems which are clearly not of their own design to determine policies and practices which ensure the cultural safety of their own people.[96]

In order to better identify potentially threatening social environments, practitioners developed the concept of cultural risk. Studies have shown that youth who experience discrimination are at higher risk for illness and infection.[97] "Such young people may include youth of color, those from low-income families, immigrants, and gay, lesbian, bisexual, and transgender (GLBT) youth. . . . Prejudice and discrimination, at individual and institutional levels, contribute to high morbidity and mortality rates among youth."[98] Further, "[r]esearch suggests that Black and Latino LGBT people are more likely to have poor health than other LGBT populations."[99]

Such risk is not limited to the young. For example, in 2000, the Chicago Task Force on LGBT, in a survey of aging persons over fifty-five "identified a number of barriers to receiving appropriate care from both health care and social service providers that were specific to their sexual orientation and/or

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[94] *See* Elaine Papps & Irihapeti Ramsden, *Cultural Safety in Nursing: The New Zealand Experience*, 8 INT'L J. QUALITY HEALTH CARE 491 (1996), *available at* http://intqhc.oxfordjournals.org/cgi/reprint/8/5/491.

[95] *Id.*

[96] *Id.* at 491-97.

[97] L. LAURA DAVIS, ADVOCATES FOR YOUTH, ADOLESCENT SEXUAL HEALTH AND THE DYNAMICS OF OPPRESSION: A CALL FOR CULTURAL COMPETENCY 1 (2003), http://www.advocatesforyouth.org/publications/iag/oppression.pdf.

[98] *Id.*

[99] *See* BOSTON PUB. HEALTH COMM'N, DOUBLE JEOPARDY: HOW RACISM AND HOMOPHOBIA IMPACT THE HEALTH OF BLACK AND LATINO LESBIAN, GAY, BISEXUAL, AND TRANSGENDER (LGBT) COMMUNITIES (2002), http://www.lgbthealth.net/downloads/research/BPHCLGBTLatinoBlackHealthDispar.doc .

gender identity."[100] Issues of biological and psychological health are but some of the critical aspects of growth and survival among individuals and kinship families.

Results of a 2006 national study indicated that there is widespread psychological and social harm inflicted on same-sex couples because they are denied the right to marry.[101] The researchers referred to this social harm through the denial of marriage as *minority stress*, which includes social isolation, stigma and shame—all of which undermine a sense of life meaning, morale, and well-being.[102]

VI. THE PROPOSED THEORIES TO AID KINSHIP FAMILIES

A. Contracts and Various Formulations

Many authors propose that private contracts should be the vehicle for re-ordering the way in which benefits are distributed.[103] For instance, Professors Rasmusen and Stake

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[100] Dennis Beauchamp et al., LGBT Persons in Chicago: Growing Older: A Survey of Needs and Perceptions 3, http://www.lgbthealth.net/downloads/research/ChicagoAgingReport2003.doc (last visited Oct. 12, 2008).

[101] *See generally* Gilbert Herdt & Robert Kertzner, *I Do, but I Can't: The Impact of Marriage Denial on the Mental Health and Sexual Citizenship of Lesbians and Gay Men in the United States*, 3 J. NAT'L SEXUALITY RES. CTR. 33, 34 (2006), *available at* http://nsrc.sfsu.edu/sites/default/files/existing_content/satcher.pdf. Some researchers refer to minority stress as historical trauma. *See generally* Bailey & Letiecq, *supra* note 53, at 22-25.

[102] Herdt & Kertzner, *supra* note 101, at 38-41.

[103] Eric Rasmusen & Jeffrey Evans Stake, *Lifting the Veil of Ignorance: Personalizing the Marriage Contract* 73 IND. L. J. 453, 500 (1998). Pamela Laufer-Ukeles postulates that marriage should no longer be a legally-protected institution, but rather should be matter of private contract and property; a different form of support structure in which caretaking is central should be developed at the center of family law. Pamela Laufer-Ukeles, *Selective Recognition of Gender Difference in the Law: Revaluing the Caretaker Role*, 31 HARV. J.L. & GENDER 1, 17 (2008); *see* MARTHA ALBERTSON FINEMAN, THE NEUTERED MOTHER, THE SEXUAL FAMILY AND OTHER TWENTIETH CENTURY TRAGEDIES 70 (1995).

> Gender neutrality has substantive implications and signals a change in orientation in which caretaking is devalued and biological and economic connection are deemed of paramount importance.
>
> There are no longer formally different expectations for, or responses to, mothers and fathers in much of family law. However, it is my contention that

observe that "marriage today is considered much more a matter for the two parties concerned, not for society, to structure."[104] As they note, one size does not fit all.[105] They acknowledge that since many who marry are not sophisticated enough to be familiar with all the ramifications of an agreement, the legislature should provide contract forms that indicate options.[106] Since they recognize the possibility of legislatures setting normative values, the forms, according to Rasmusen and Stake, should allow individuals to "structure their lives as they wish."[107]

Distinct from Rasmusen and Stake, Professor Zelinsky

> in practice the egalitarian rhetoric of modern reforms results in unrealistic, punitive responses that are harmful to mothers and children.

Id. (footnote omitted). In addition, Melissa Murray states in her article:

> [J]ust as cohabitation agreements and the like have been used to secure some of the benefits of marriage to unmarried couples, private contracts still might be a promising way to provide benefits and some sort of legal recognition to nonparental caregivers.
>
> As a general matter, the recent expansion of the legal concept of parenthood to include functional parents and multiple third parties, in tandem with the use of private agreements in structuring the provision of nonparental care, all are important developments in moving towards greater recognition of the caregiving continuum.

Melissa Murray, *The Networked Family: Reframing the Legal Understanding of Caregiving and Caregivers*, 94 VA. L. REV. 385, 444 (2008). The author suggests that private marriages may "simply resurrect the private character of caregiving and shield nonparental caregiving efforts from public view. Thus, if we are interested in developing a theoretical framework that would encompass the continuum between parents and strangers, the expansion of parenthood through these vehicles may be too limited." *Id.* at 447; *see also* David Boaz, *Privatize Marriage: A Simple Solution to the Gay-Marriage Debate*, SLATE, Apr. 25, 1997, http://www.slate.com/id/2440/.

[104] Rasmusen & Stake, *supra* note 103, at 500. In the past, religion and society defined the gender roles in a marriage. *Id.* This type of marriage did not allow for simple dissolution or roles that differed from those defined. *Id.* With changing times, the opinion on marriage has changed and "restraints on individual liberty have weakened or disappeared." *Id.*

[105] *Id.* at 501. To be specific, this article states that no-fault divorce does not necessarily fit all situations because there may be problems with identifying the grounds for divorce. *Id.* Furthermore, in an age when familial and social norms have weakened, "people need legal institutions to pick up the slack, allowing them to make credible commitments to each other." *Id.* People need to know to what extent their marriages are enforceable by law for the marital bonds to remain traditional between spouses. *Id.*

[106] *Id.* at 502.

[107] *Id.*

focuses on the free market as a source for contracts. As he notes, adopting a contractual approach will democratize marriage.[108] Secular and religious organizations will offer various prototypical contracts as models.[109] Further analogizing to prenuptial agreements, [110] Zelinsky argues that utilizing contracts does not vary that much from what already exists.[111]

Certainly, the wealthy frequently engage in such pre-planning.[112] According to some sources, the majority of marriages will be preceded by a prenuptial agreement by 2020.[113] "At the New York-based Equality in Marriage Institute, . . . a nonprofit that advises couples, the number of

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[108] Edward A. Zelinsky, *Deregulating Marriage: The Pro-Marriage Case for Abolishing Civil Marriage*, 27 CARDOZO L. REV. 1161, 1182 (2006).

> [A] deregulated marital regime would require default rules for those couples who fail to contract and for those couples whose contracts fail to address particular issues. Any contract regime, including one for marital and cohabitation agreements, must decide who can contract and when their deals violate public policy. Determining these default rules and the contours of public policy will be contentious in a heterogeneous and democratic polity like the United States at the beginning of the twenty-first century, but not nearly as contentious as the status quo of civil marriage.

Id. (footnote omitted).

[109] *Id.* at 1182. Marriage contracts could be as individually tailored as other contracts are in our diverse capitalist world. *Id.* For those who wanted a standard one-size-fits-all contract, that would still be easy to obtain. Boaz, *supra* note 103. "Wal-Mart could sell books of marriage forms next to the standard rental forms." *Id.*

[110] *Id.* at 1176. The prenuptial agreement bears similarities to the statutory declaration currently signed by covenant marriage couples. *Id.* The current declaration signifies "commitment to a 'lifelong relationship.'" *Id.* The prenuptial agreement would limit divorces in the same way covenant marriage statutes do. *Id.*

[111] *Id.* at 1184. Similar to any other contract, a domestic-based contract will need an age of consent to determine capability of entering into the marital contract. *Id.*

[112] Beth Potier, *For Many, Prenups Seem to Predict Doom*, HARV. U. GAZETTE, Oct. 16, 2003, http://www.hno.harvard.edu/gazette/2003/10.16/01-prenup.html. "Often considered exclusive to the very wealthy, 'prenuptial agreements can go beyond preserving assets before the marriage' . . . . They might dictate custody arrangements, for instance, or decree that despite most states' 'no-fault' divorce laws, the couple agrees to divorce only in the presence of the traditional grounds of fault like abuse, addiction, or imprisonment." *Id.*; *see also* LovetoKnow.com, Prenuptial Agreements: Interview with Helene Taylor, http://divorce.lovetoknow.com/Prenuptial_Agreements:_Interview_with_Helene_Taylor (last visited Apr. 10, 2009).

[113] ARLENE G. DUBIN, PRENUPS FOR LOVERS: A ROMANTIC GUIDE TO PRENUPTIAL AGREEMENTS, http://www.prenupsforlovers.com/definition.php (last visited Oct. 12, 2008).

inquiries about prenups from both men and women has climbed from 1,500 a month in 2003 to some 5,000 a month . . . ." in 2006.[114] Twenty-six states have already adopted a version of the Uniform Agreement Act which governs prenuptial agreements.[115]

Prenuptials should not be thought of as just for the wealthy. Sometimes prenuptials contain requirements that control almost every facet of everyday living. For instance, a prenuptial agreement by a New Mexican couple required them to only pay cash unless the other spouse agreed to do otherwise and to not leave anything on the floor overnight unless one party was packing.[116] Further, it is not an expensive proposition to draft a prenuptial agreement; they are available online.[117] Prenuptial forms ask questions about property, debts, children and support in case of separation. Both parties decide what they think 'marriage' should refrain from, contain or be restricted to.[118]

Related to prenuptials are common law marriages, which also have a contractual concept underlying the non-written

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[114] Kerry Hannon, *Planning for Love and Money*, U.S. NEWS & WORLD REP., July 16, 2006, at 53, *available at* http://www.usnews.com/usnews/biztech/articles/060716/24prime.htm.

[115] UNIF. LAW COMM'RS: THE NAT'L CONFERENCE OF COMM'RS ON UNIF. STATE LAWS, FACT SHEET: UNIFORM PREMARITAL AGREEMENT ACT, http://www.nccusl.org/Update/uniformact_factsheets/uniformacts-fs-upaa.asp (last visited Oct. 12, 2008).

[116] Gary Belsky, *Living by the Rules*, MONEY MAG., May 1, 1996, at 100, *available at* http://money.cnn.com/magazines/moneymag/moneymag_archive/1996/05/01/212090/index.htm. The New Mexico couple further contractually agreed to "[n]ever follow the car in front of them by less than one car length for every 10 miles per hour they are traveling" and to "[a]lways have 'healthy' sex three to five times a week." *Id.* This agreement, however, is beyond the normal agreement that spouses sign upon marriage. *Id.* It is detailed in areas from the number of children they will have to the kind of gas they will use. *Id.* The couple believed that agreeing to terms that typically cause fights in a marriage would alleviate arguments because all the areas were already decided upon. *Id.* They maintain their theory because the couple has not fought since they were married. *Id.* If the couple faces times where their plan does not work out as they anticipated, they have stated they are able to expand the agreement because "'it's a living document.'" *Id.*

[117] *See* LawDepot.com, Prenuptial Agreement, http://www.lawdepot.com/contracts/prenup/ (last visited Apr. 10, 2009).

[118] *Id.*

agreement to cohabitate. Some feminist scholars advocated, at least ten years ago, that a common law approach addressed many of the concerns that "typical marriages presented."[119] The theme was that common law marriages protected women who were not formally married.[120] The scholars advocated extending or re-introducing common law marriages to all states.[121]

Historically, various states tolerated and embraced common-law marriages.[122] Unfortunately with the abolition of slavery, many states eliminated common law marriages because of the fear of interracial marriage.[123] Later, in the roaring 1920's, the "'lax" morals contributed to apprehension that the institution of marriage was being threatened, thus states again outlawed more common law marriage provisions.[124] Finally, the growth of governmental benefits made some officials worry about how to administer claims if common law marriages were allowed.[125] Thus, currently only eight states and the District of Columbia formally recognize the institution without conditions other than the couple cohabitate and hold themselves out as being married.[126] Unlike the squabble that is currently taking

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[119] *See generally* Cynthia Grant Bowman, *A Feminist Proposal to Bring Back Common Law Marriage*, 75 OR. L. REV. 709 (1996).

[120] *Id.* at 711.

[121] *See id.* "[A] common law 'widow' . . . [cannot] collect Social Security survivors' benefits after a relationship of very long standing and thus [must] rely upon public benefits providing much less income . . . ." *Id.* The "widow" is also "unable to collect damages for a wrongful death action." *Id.*

[122] *Id.* at 719-20. "With the reception of English common law in the American colonies, common law marriage was transferred to this continent, where some states embraced the doctrine and others did not." *Id.* at 719. From as early as 1639, Puritans in Massachusetts had established statutes and regulations governing entry into marriage. *Id.*

[123] *Id.* at 740, 745. *See* Loving v. Virginia, 388 U.S. 1 (1967) (overruling Naim v. Naim, 87 S.E.2d 749, 756 (1955), where purposes were "to preserve the racial integrity of its citizens," prevent "the corruption of blood," "a mongrel breed of citizens," and "the obliteration of racial pride," and finally to endorse the doctrine of White Supremacy).

[124] Bowman, *supra* note 119, at 743-44.

[125] *Id.* at 746-48.

[126] ALTERNATIVES TO MARRIAGE PROJECT, FACT SHEET: COMMON LAW MARRIAGE, http://www.unmarried.org/commonlaw.pdf (last visited Apr. 10, 2009); *see also* Bowman, *supra* note 119, at 749. States that recognize common law marriage include: Georgia—if created before 1/1/97—GA. CODE ANN. § 19-3-1.1 (2004); Idaho—if created before 1/1/96—IDAHO CODE § 32-201 (2006); Iowa, IOWA CODE ANN. §. 595.11 (West 2001); Kansas, KAN.

place with regard to same-sex marriages, the states that do not recognize common law marriage within their own state, frequently declare these unions as valid even though formalized in another state.[127] The states follow the principles set in the United States Constitution that requires every state to accord "Full Faith and Credit" to the laws of its sister states.[128]

As with prenuptial agreements, there are many samples of an agreement or contract to be used by people considering common law marriages in order "to avoid court imposed support payments or division of property" and "to avoid conflict during the relationship or upon its breakdown" as to "property

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STAT. ANN. § 23-101 (2007); Montana, MONT. CODE ANN. § 40-1-403 (2007); New Hampshire—for inheritance purposes only—N.H. REV. STAT. ANN. § 457:39 (2008); Oklahoma—possibly only if created before 11/1/98—OKLA. STAT. ANN. tit. 43, § 1 (West 2001); Pennsylvania—if created before 1/1/05—23 PA. CONS. STAT. ANN. § 1103 (2007); Texas, TEX. FAM. CODE ANN. § 2.401 (1998); Utah, UTAH CODE ANN. § 30-1-4.5 (2007); Alabama, Piel v. Brown, 361 So. 2d 90, 93 (Ala. 1978); Colorado, Deter v. Deter, 484 P.2d 805, 806 (Colo. Ct. App. 1971); Ohio—if created before 10/10/91—Lyons v. Lyons 621 N.E.2d 718, 720 (Ohio Ct. App. 1993); Rhode Island, Sardonis v. Sardonis, 261 A.2d 22, 24 (R.I. 1970); South Carolina, Johnson v. Johnson, 112 S.E.2d 647, 651 (S.C. 1960); and Washington D.C., Johnson v. Young, 372 A.2d 992, 994 (D.C. 1977).

[127] NAT'L CONFERENCE OF STATE LEGISLATURES, COMMON LAW MARRIAGE, http://www.ncsl.org/programs/cyf/commonlaw.htm (last visited Oct. 15, 2008). The Seattle Mayor's executive order which required city departments to recognize same-sex marriages of city employees for purposes of employee benefits, did not directly conflict with the State's Defense of Marriage Act which defines marriage as a civil contract between a male and a female. Leskovar v. Nickels, 166 P.3d 1251, 1255 (Wash. Ct. App. 2007). The order merely determined who was eligible for employee benefits without giving legal effect to same-sex marriages, though the order contained language in its "whereas" clauses stating that "marriage equality should be afforded to all consenting, adult couples regardless of their sexual orientation." *Id.* at 1256. The executive order which required county agencies to recognize same-sex marriages that were validly contracted out-of-state was an implementing device and not a law, and, therefore, it does not violate the constitutional provision which empowered local governments to adopt laws not inconsistent with the state constitution and general law. Godfrey v. Spano, 836 N.Y.S.2d 813, 819 (Sup. Ct. 2007). A taxpayer could not show any injury-in-fact resulting from state university's policy of providing health benefits to same-sex domestic partners of its employees based solely upon being a taxpayer. Brinkman v. Miami Univ., No. CA2006-12-313, 2007 WL 2410390, at *3 (Ohio Ct. App. Aug. 27, 2007). Therefore, he did not have common-law taxpayer standing to seek prospective declaratory and injunctive relief to prevent his tax dollars from being used to finance the benefits. *Id.* Even though many states are claiming that DOMA overrides Full Faith and Credit within states, courts have determined that same-sex benefits and marriages do demand recognition. *See infra* note 134.

[128] U.S. CONST. amend. IV, § 1.

ownership, debt obligations, and support obligations."[129] These agreements frequently ask questions regarding property, inheritance, gifts from third parties, insurance policies' details, law suit awards, debts, support and for how many years, estate matters and income and savings.[130] While some say that planning for what happens if there is a divorce, separation or death when entering a kinship arrangement puts a pale on the concept of marriage, others advocate that all persons seeking to enter such a union have mandatory planning in case divorce results.[131] Taken from another perspective, pre-nuptial planning and contractual agreements may be a significant process in building the relationship. Such a process would require a thoughtful dialogue about highly important matters such as money, family, location and attributes of home, work, children, blended family issues, pets, celebration of holidays and religious practices, and even sexual relations.

Despite the historical move to non-recognition of common law marriages, as Professor Bowman points out, courts now engage in broadly interpreting statutes to award non-married

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[129] *See* LawDepot.com, Common Law Partner Agreement, http://www.lawdepot.com/contracts/common-law-partner-agreement/ (last visited Apr. 10, 2009).

[130] *Id.*; *see also* USLegalForms.com, Prenuptial Agreement Forms, http://www.uslegalforms.com/premarital/ (last visited Oct. 13, 2008); FindLaw.com, Sample Premarital/Prenuptial Agreement, http://family.findlaw.com/marriage/marriage-resources/le19_4_1.html (last visited Oct. 13, 2008).

[131] Jeffrey Evans Stake, *Mandatory Planning for Divorce*, 45 VAND. L. REV. 397, 425 (1992). Professor Carol Sanger, even though a contracts expert, is one of the most articulate critics of contracts as a solution. *See generally* Carol Sanger, *A Case for Civil Marriage*, 27 CARDOZO L. REV. 1311 (2006). Although much of what she argues in her article is directed at using contracts as a basis for same-sex couplings, her critique extends beyond that exclusive category. *Id.* She worries about full disclosure, people being bound by their contracts whether they have read them or not and utilizing "fillers" to complete the indefinite portions. *Id.* at 1313-15. Sanger wonders if "the law of marriage contract will over time not differ much from the law of civil marriage." *Id.* at 1315. The presumption is that contract arrangements will turn into civil marriages. *Id.* Another concern regarding contracts is always what happens when somebody breaches. *Id.* How is a contract going to be enforced or damages awarded in complex and emotional situations? *Id.* Sanger illustrates what a mess courts would be in if there were contractual breaches. *Id.* As she observes, should a judge enjoin a defendant spouse from "marrying again, just as defecting sports players cannot sign with other teams," if that were part of the contractual agreement? *Id.*

spouses the same benefits as persons in an officially recognized marriage.[132] For instance, non-married spouses may recover as "dependants" under workers' compensation laws.[133] Some courts search for reasons to allow people to claim they were "married" using doctrines such as quasi-contract, estoppel and equitable remedies.[134] Significantly, the recognition of what constitutes a "spouse" or a member of a kinship family is given the broadest interpretation possible to get to the desired results. As another indication of even a state legislature's willingness to expand the definition of family, Hawaii's wrongful death statute allows people to enter into a contract designating who is to be a 'reciprocal beneficiary.'[135] Not only can a contract be the basis of wrongful death claims, but Hawaii has also been very inclusive of who may make a claim under the statute.[136] According to court interpretation, both a legal family and a common law family can simultaneously collect damages.[137] Further, any dependent or partially dependent person can also collect.[138] The Hawaiian interpretation of what constitutes family is a model for all states.[139]

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[132] Bowman, *supra* note 119, at 763.

[133] Peoples-law.org, Benefits, Insurance, Inheritance and Taxes, http://www.peoples-law.org/family/Unmarried%20Cohabs/cohabs%20benefits%20-%20wlc.htm (last visited Apr. 20, 2009). Maryland entitles workers' compensation benefits to unmarried survivors based on a dependency standard. MD. CODE ANN., LAB. & EMPL. § 9-678 (LexisNexis 2008). An unmarried cohabitant who can show that he or she was wholly or partly dependent on the deceased employee at the time of the lethal injury will receive benefits. *Id.*

[134] Bowman, *supra* note 119, at 770.

[135] HAW. REV. STAT. § 572 C-1, -6 (2006). Note that the statute does not provide reciprocal beneficiaries compensation in the event of severe and permanent injury. *See* Sarah M. Love, Comment, *Extending Loss of Consortium to Reciprocal Beneficiaries: Breaking the Illogical Boundary Between Severe Injury and Death in Hawai'i Tort Law*, 28 U. HAW. L. REV. 429, 430 (2006).

[136] Lealaimatafao v. Woodward-Clyde Consultants, 867 P.2d 220 (Haw. 1994).

[137] *Id.* at 224.

[138] *Id.* Contrast with Florida where the wrongful death act only allows "survivors" to collect from an award. FLA. STAT. ANN. § 768.20 (West 2005). "Survivors" are defined as the surviving spouse, minor children, parents and any blood relatives and adoptive brothers and sisters who are partly or wholly dependent on the deceased. § 768.18.

[139] HAW. REV. STAT. § 587-2 (2006).

> "Family" means each legal parent, the natural mother, the natural father, the adjudicated, presumed, or concerned natural father as defined under section

Hawaii is not alone. In California, which does not officially recognize common law marriages,[140] courts have substituted "palimony" relationships and consider the oral promises as binding contracts.[141] As actor Lee Marvin found out, his oral promise with his non-marital partner, Michelle, was held to be a binding contract, and he was forced to give her one-half of the property accumulated during the period they lived together.[142] According to the court, an oral contract involving earnings and property rights between people, even those who have sex with each other, is enforceable.[143] The court quite willingly used equitable principles and quantum meruit to permit recovery.[144]

VII. WHAT CAN LEGISLATION ACHIEVE?

"The state cannot create healthy relationships; it can only seek to foster the conditions in which close personal relationships that are reasonably equal, mutually committed, respectful and safe can flourish."[145]

The concept of legislative protection and recognition of kinship families encounters many of the same legal and societal obstacles that confront the recognition of same-sex relationships. Indeed, the need for state recognition of these relationships arises not just from human intimacy, but also from human dependency. If states do not provide adequate legal protection for ordinary and loving human relations and continue to limit

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578-2, each parent's spouse, or former spouses, each sibling or person related by consanguinity or marriage, each person residing in the same dwelling unit, and any other person who or legal entity which is a child's legal or physical custodian or guardian, or who is otherwise responsible for the child's care, other than an authorized agency which assumes such a legal status or relationship with the child under this chapter.

Id.

[140] Marvin v. Marvin, 557 P.2d 106, 122 n.24 (Cal. 1976).

[141] *Id.* at 122-23.

[142] *Id.* at 116.

[143] *Id.* at 113.

[144] *Id.* at 110, 122-23.

[145] LAW COMM'N OF CAN., BEYOND CONJUGALITY: RECOGNIZING AND SUPPORTING CLOSE PERSONAL ADULT RELATIONSHIPS xxiii (2001), *available at* http://www.samesexmarriage.ca/docs/beyond_conjugality.pdf [hereinafter BEYOND CONJUGALITY].

comprehensive legal protection to heterosexual adults or conjugal relationships, the state will undermine financial, emotional and societal support of caregivers, who are typically women.[146] Providing legal protections for the social arrangements constructed by adults and their chosen beneficiaries allows individuals to construct their own viable family units to protect and promote their mutual interests and further acknowledges the interdependence of all human relationships.[147]

Although private contracts provide some legal protection, a more practical solution is to allow individuals to undertake a series of legal obligations by entering into a public legal arrangement recognized by state, national and international laws. While private contracts can structure the legal aspects of a kinship relationship, such private arrangements are problematic.[148] First, it is difficult to anticipate all of the situations in which the legality of kinship arrangements will be relevant. Second, many parties lack the financial means to create the legal arrangements to confer recognizable duties and

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[146] *See* Martha Albertson Fineman, *Cracking the Foundational Myths: Independence, Autonomy, and Self-Sufficiency*, 8 AM. U. J. GENDER SOC. POL'Y & L. 13, 18 (2000). Professor Fineman asserts:

> [T]he caretaking work creates a collective or societal debt. Each and every member of society is obligated by this debt. Furthermore, this debt transcends individual circumstances. In other words, we need not be elderly, ill, or children any longer to be held individually responsible. Nor can we satisfy or discharge our collective responsibility within our individual, private families. Merely being financially generous with our own mothers or duly supporting our own wives will not suffice to satisfy our share of the societal debt generally owed to all caretakers.

Id.

[147] *See id.* Some have argued that "[t]he medieval church instituted marriage laws and practices that undermined large kinship groups. . . . [Thus], by the late medieval period the nuclear family was dominant [sic]." AVNER GREIF, FAMILY STRUCTURE, INSTITUTIONS, AND GROWTH: THE ORIGIN AND IMPLICATIONS OF WESTERN CORPORATISM 2-3 (2005) (footnote omitted), *available at* http://www.aeaweb.org/annual_mtg_papers/2006/0106_0800_1104.pdf.

[148] *See* BEYOND CONJUGALITY, *supra* note 145, at 115. "The contractual model may respect the value of autonomy but often falls short of fulfilling other values such as equality or efficiency since too few individuals are prepared to negotiate the terms of their close personal relationships." *Id.*

obligations.[149] Third, legal status facilitates recognition of such arrangements in a variety of contexts.[150]

In addition, extending marriage rights outside of marriage provides legal visibility for important social and economic relationships.[151] Even with carefully planned legal arrangements, a surviving companion can become a legal stranger under existing laws because such individuals are not considered "next of kin."[152] These laws affect hospital visitation rights, funeral arrangements and permitted medical disclosures. As Nancy Knauer concluded, "I cannot protect my chosen family in the absence of some form of uniform relationship status on both the state and federal level."[153]

At the core of extending marriage rights to unmarried persons is the legal protection of units identified as families so that they can share resources, benefits, duties and obligations on a consensual basis. Accordingly, the government regulation of marriage essentially involves a contractual relationship. Marriage has maintained a privileged legal status in the United States. Laws in almost all states limit contractual choice of marriage to heterosexual couples.[154] In addition, constitutional

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[149] *Id.*

[150] *Id.* at xxiii.

[151] *See* Nancy J. Knauer, *A Marriage Skeptic Responds to the Pro-Marriage Proposals to Abolish Civil Marriage*, 27 CARDOZO L. REV. 1261, 1272-73 (2006).

[152] *Id.*

[153] *Id.* at 1276.

[154] *See*, NEW DIRECTIONS FOR FAMILY LAW IN THE UNITED STATES: FROM CONTRACT COHABITATION TO REGISTERED PARTNERSHIPS AND BEYOND 12 (2007) http://www.indret.com/pdf/430_en.pdf. "Normally, contract law assumes freedom of contract, party autonomy, and equal bargaining power. The marriage contract is not totally free of governmental regulation and therefore parties have limited freedom of choice." *Id.*; *see also* SANFORD N. KATZ, FAMILY LAW IN AMERICA 36-37 (2003). As of November 4, 2008, only two states, Connecticut and Massachusetts, permit same-sex marriages. Lambda Legal.org, Status of Same-Sex Relationships Nationwide, http://www.lambdalegal.org/publications/articles/nationwide-status-same-sex-relationships.html (last visited Apr. 10, 2009) (including California's constitutional ban of same-sex marriage on November 4, 2008) [hereinafter Lambda Legal]. Following this report, Iowa and Vermont also recognized same-sex marriage. The Iowa Supreme Court decided denial of same-sex marriage violated equal protection of the law. Varnum v. Brien, No. 07-1499, 2009 WL 874044 (Iowa Apr. 3, 2009). The Vermont Legislature overrode the Governor's veto and now recognizes same-sex marriage also. Abby Goodnough & Katie Zezima, *Rejecting Veto, Vermont Backs Gay Marriage*, N.Y. TIMES,

provisions in twenty-nine states ban same-sex marriage.[155] As a result, obstacles to legal recognition of same-sex couples have acted to impede the provision of similar recognition and benefits for other adult relationships.

A. What Legal Rights Should Be Conferred?

The federal benefits, rights and privileges that were enumerated by the GAO have functioned to promote and protect the family unit and need recognition and reproduction in kinship relationships.[156] Persons who choose to pool their resources within a household or similar unit need legal protection, support and recognition of those relationships.[157] Apart from marriage and private contracts, government can provide protection to relationships of cohabitating adults through legal recognition and/or the provision of legal benefits to such adults.[158] Two possible ways to accomplish these goals

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Apr. 8, 2009, at A1.

[155] Lambda Legal, *supra* note 154. Recently, on November 4, 2008, three more states—Arizona, California and Florida—adopted constitutional bans on same-sex marriage. John Gramlich & Christine Vestal, *3 States, Including Calif., Ban Gay Marriage*, STATELINE.ORG, Nov. 7, 2008, http://www.stateline.org/live/details/story?contentId=353318 ("California's vote calls into question 18,000 marriage licenses granted to same-sex couples since they won the right to wed under a court ruling six months ago."). With these bans, thirty states (if Hawaii is included) have constitutional bans on same-sex marriage. *Id.* Gay rights sources, however, place the number of states with a constitutional ban at twenty-nine and include Hawaii as one of fifteen states that have law prohibiting same-sex marriage. *See* Human Rights Campaign, Statewide Marriage Prohibitions, Nov. 17, 2008, http://www.hrc.org/documents/marriage_prohibitions.pdf (reflecting the recent constitutional ban in California); Lambda Legal, *supra* note 154. Hawaii is often omitted from the lists of states with constitutional bans on marriage because Hawaii's constitutional amendment did not ban same-sex marriage per se. The amendment, however, allows the Hawaiian legislature to restrict marriage to opposite-sex couples. Haw. Const. Art. I, § 23.

[156] Shah, *supra* note 30, at 3.

[157] *See* Martha Albertson Fineman, *Progress and Progression in Family Law*, 2004 U. CHI. LEGAL F. 1, 4. Professor Fineman notes that "Of particular importance for policymakers should be family units that are caring for children, the elderly, or the ill. In our family ideology it is the marital family that is assigned responsibility for the caretaking of dependant individuals. This family is the way we 'privatize' dependency." *Id.*

[158] Acey, *supra* note 29, at 1-5.

would be to extend domestic partnership registration or domestic partnership benefits to non-conjugal cohabitating adults in kinship relationships.

B. Registration: Domestic Partnership Law Model

Domestic partnership law offers a registration model that can be extended to kinship relationships.[159] As such, domestic partnership law has begun the task of recognizing the importance of kinship units outside of the conjugal heterosexual model. With domestic partnership law comes the recognition that adults may choose to share their lives for a variety of reasons and that the recognition of such family relations can benefit society. Still, these models foster, in part, legal relationships among unrelated adults even though adult relationships among related individuals continue to be an important outgrowth of our "traditional" nuclear families.[160] Nevertheless, domestic partnership laws have opened the door to addressing the need for laws applicable to kinship family units that provide mutual support and care for adults and their loved ones. Currently, however, domestic partnership laws usually provide legal recognition of only quasi-marital relationships.[161]

1. Conjugal Aspect

Many of the current domestic partnership laws provide protections for individuals in a conjugal relationship, that is, individuals functioning as a "couple."[162] In so doing, these laws provide legal protections to relationships that mimic marriage.

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[159] BEYOND CONJUGALITY, *supra* note 145, at 117-19.

[160] *See* Nancy D. Polikoff, *Making Marriage Matter Less: The ALI Domestic Partner Principles Are One Step in the Right Direction*, 2004 U. CHI. LEGAL F. 353, 355.

[161] *See* Thomson Reuters/West, *Effects of Civil Unions / Domestic Partnerships on Benefits at the State Level*, 50 State Statutory Surveys, Dec. 2008, at 1.

[162] THE AM. LAW INST., PRINCIPLES OF THE LAW OF FAMILY DISSOLUTION: ANALYSIS AND RECOMMENDATIONS § 6.03 (2002). For example, The American Law Institute states that "domestic partners are two persons of the same or opposite sex, not married to one another, who for a significant period of time share a primary residence and a life together as a couple." *Id.*

While these provisions offer much needed protection to a host of intimate relationships, they exclude relationships that are not consecrated on sexual intimacy or that do not replicate married couples' relationships.[163] Typically such laws are put in place to provide legal recognition of same-sex couples and/or to provide an option similar to marriage for heterosexual couples.[164]

Most domestic partnership laws, in the United States and other nations, provide registration primarily for same-sex partners.[165] Typically, such schemes require a common residence, prohibit the registration of persons related by blood and only include opposite-sex partners involving persons at least sixty-two years old.[166]

As stated in *Beyond Same-Sex Marriage*, "[a]ll families, relationships, and households struggling for stability and economic security will be helped by separating basic forms of legal and economic recognition from the requirement of marital and conjugal relationship."[167] This document later explains that "[t]o have our government define as 'legitimate families' only those households with couples in conjugal relationships does a tremendous disservice to the many other ways in which people actually construct their families, kinship networks, households, and relationships."[168] Thus, allowing persons to share in rights afforded to married partners provides security and stability for non-traditional family arrangements. Accordingly, *Beyond Same-Sex Marriage* asserts that "[m]arriage is not the only worthy form of family or relationship, and it should not be legally and economically privileged above all others."[169] In sum, the purpose of extending legal recognition to non-marital relationships is to limit or eliminate marriage privileges that create legal discrimination or disparate treatment for kinship families that are not bound by marriage or similar

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[163] BEYOND CONJUGALITY, *supra* note 145, at 119.

[164] *See* Thomson Reuters/West, *supra* note 161.

[165] BEYOND CONJUGALITY, *supra* note 145, at 117.

[166] *See* CAL. FAM. CODE § 297 (b) (West 2004); N.J. STAT. ANN. § 26:8A-4 (West 2007).

[167] Acey, *supra* note 29, at 1.

[168] *Id.* at 2.

[169] *Id.*

arrangements.[170]

2. Non-Blood Relationships

Domestic partnership law arose out of a need to provide legal recognition of and protection for the consensual arrangements of unmarried couples.[171] Due to this focus, the domestic partnership laws attempt to provide limited legal protections for heterosexual or same-sex couples who do not or, in the case of same-sex couples, cannot legally marry.[172] As a result, such laws typically would not afford protections for kinship relationships amongst related adults. Thus, these laws would exclude important kinship relationships.

3. Reciprocal Benefit Arrangements

Both Hawaii and Vermont have laws that provide for reciprocal beneficiaries.[173] Each of these laws allows unmarried adults to share some benefits and protections that were previously afforded only to spouses.[174] If individuals meet the

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[170] *Id.*

> Autonomy is compromised if the state provides one relationship status with more benefits and legal support than others, or conversely, if the state imposes more penalties on one type of relationship than it does on others. It follows then that an important corollary of the value of relational autonomy is a principle of state neutrality regarding the form or status that relationships take. The state ought to support any and all relationships that have the capacity to further relevant social goals, and to remain neutral with respect to individuals' choice of a particular form or status.

BEYOND CONJUGALITY, *supra* note 145, at 18.

[171] BEYOND CONJUGALITY, *supra* note 145, at 117.

[172] *Id.* For example, the domestic partnership laws in California and New Jersey require a common residence and exclude related individuals. *See* CAL. FAM. CODE § 297 (West 2004) (operative Jan. 1, 2005); N.J. STAT. ANN. § 26:8A-4 (West 2007). For an overview of municipal and county domestic partnership law in the United States, see William C. Duncan, *Domestic Partnership Laws in the United States: A Review and Critique*, 2001 BYU L. REV. 961, 965-78.

[173] HAW. REV. STAT. § 572C (2006); VT. STAT. ANN. tit. 15, §§ 1301-05 (2002).

[174] HAW. REV. STAT. §§ 572C-1 to -7; VT. STAT. ANN. tit. 15, §§ 1301-05. As one author notes:

> The Hawaii law provides a number of benefits to state employees and citizens, although its effect on private employers is limited. Its provisions include funeral leave for state employees, hospital visitation rights, health insurance coverage for partners of state employees, and the ability to claim an elective

criteria specified in the statute, they may establish a reciprocal beneficiaries relationship by signing a declaration.[175] The reciprocal beneficiaries criteria address some of the moral concerns for not legally recognizing such relationships by providing a minimum age of consent,[176] prohibiting polygamy[177] and requiring consent to the arrangement.[178] Along these lines, such statutes recognize to some degree the economic dependency that may exist among unmarried adults.[179]

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share of a partner's estate.

Duncan, *supra* note 172, at 963. For a fuller explanation of the rights of reciprocal beneficiaries under Hawaiian law, see W. Brian Burnette, Note, *Hawaii's Reciprocal Beneficiaries Act: An Effective Step in Resolving the Controversy Surrounding Same-Sex Marriage*, 37 BRANDEIS L.J. 81, 87-89 (1998). Section 1301 of the Vermont statute limits benefits to the following specific areas:

(1) Hospital visitation and medical decision-making under 18 V.S.A. § 1853;

(2) Decision-making relating to anatomical gifts under 18 V.S.A. § 5240;

(3) Decision-making relating to disposition of remains under 18 V.S.A. § 5220;

(4) Durable power of attorney for health care under 14 V.S.A. § 3456 and terminal care documents under 18 V.S.A. § 5254;

(5) Patient's bill of rights under 18 V.S.A. chapter 42;

(6) Nursing home patient's bill of rights under 33 V.S.A. chapter 73;

(7) Abuse prevention under 15 V.S.A. chapter 21.

15 VT. STAT. ANN. tit. § 1301(a).

[175] HAW. REV. STAT. ANN. § 572C-4. The requirements of the Hawaii statute are as follows:

(1) Each of the parties be at least eighteen years old;

(2) Neither of the parties be married nor a party to another reciprocal beneficiary relationship;

(3) The parties be legally prohibited from marrying one another under chapter 572;

(4) Consent of either party to the reciprocal beneficiary relationship has not been obtained by force, duress, or fraud; and

(5) Each of the parties sign a declaration of reciprocal beneficiary relationship as provided in section 572C-5.

Id. The Vermont statute has similar requirements, but adds an additional requirement that the parties "[b]e related by blood or by adoption . . . ." § 1303(3).

[176] § 572C-4(1); § 1303(1).

[177] § 572C-4(2); § 1303(2).

[178] § 572C-4(4); § 1303(4).

[179] *See, e.g.*, § 572C-2. Hawaii used a public policy rationale as a basis creating the necessary legislation. Section 572C-2 of the Hawaii Statutes states the findings that led to the adoption of the "Reciprocal Beneficiary" law. *Id.* This section explains that:

Since Hawaii, unlike Vermont, has not legalized same-sex unions, the Hawaiian statute has been criticized for sidestepping the issue of same-sex relationships.[180] Because the Hawaii statute did not extend the rights of marriage to same-sex couples, but only provided more limited rights within the context of domestic partnerships, it has been viewed as granting less than full equality to same-sex couples even though it affords more rights to non-conjugal relationships.[181]

Extending legal marriage privileges to same-sex and non-conjugal relationships will undoubtedly be a slow process. Just as states currently struggle with equality issues for same-sex relationships, kinship relationships will face similar challenges. Like same-sex marriages, the concerns will have religious and moral overtones that seek to limit legal recognition of non-traditional family units. The current requirements of domestic partnership[182] and reciprocal beneficiaries[183] strive to address such concerns.

C. Benefit Sharing: Domestic Partnership Designation

1. What Statutes Should Provide

As discussed above, domestic partnership law and reciprocal beneficiaries law provide models for the extension of laws supporting kinship relationships. While reciprocal

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> [T]he legislature concurrently acknowledges that there are many individuals who have significant personal, emotional, and economic relationships with another individual yet are prohibited by such legal restrictions from marrying. For example, two individuals who are related to one another, such as a widowed mother and her unmarried son, or two individuals who are of the same gender. Therefore, the legislature believes that certain rights and benefits presently available only to married couples should be made available to couples comprised of two individuals who are legally prohibited from marrying one another.

Id.

[180] *See* Grace Ganz Blumberg, *The Regularization of Nonmarital Cohabitation: Rights and Responsibilities in the American Welfare State*, 76 NOTRE DAME L. REV. 1265, 1277 (2001).

[181] *Id.* at 1277-78.

[182] *See supra* note 172 and accompanying text.

[183] *See supra* note 175 and accompanying text.

beneficiaries laws provide some legal benefits for same-sex couples and non-marital couples, they are limited.[184] At the same time, however, individuals in kinship groups may not want the full range of rights and duties accorded in domestic partnership or marriage laws.[185] Thus, kinship arrangements can range from "offering the most extensive rights and obligations" that can be offered in adult relationships to "no rights or obligations at all" between adults.[186] Between these two extremes lies the concept of the granting of benefits and entitlements that are important to share in emotionally and economically interdependent relationships.[187]

2. Developing a Methodology: The Law Commission of Canada Approach

The process of proposing legislation for kinship relationship should begin with reviewing the existing laws that use "relational terms to accomplish [their] objectives."[188] In *Beyond Conjugality*, the Law Commission of Canada proposed a four-step methodology to review existing laws based on relationships status.[189]

> The first question is whether a law is pursuing legitimate objectives that respond to social realities in a manner consistent with fundamental values. If not, the law should be repealed or revised. The second question is whether relationships even matter in a particular policy context. If the existence of relationships is not relevant to a legislative objective, then the law should not take them into account. If

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[184] *See* Blumberg, *supra* note 180 and accompanying text.

[185] For that reason, the Law Commission of Canada expressed a preference for the registration model over the ascription model for recognizing the relationships of unmarried adult cohabitants. BEYOND CONJUGALITY, *supra* note 145, at 116.

[186] S. AFR. LAW REFORM COMM'N, DISCUSSION PAPER 104: DOMESTIC PARTNERSHIPS 262 (2003), *available at* http://www.doj.gov.za/salrc/dpapers.htm (last visited Nov. 15, 2008). On this basis, the South African Law Reform Commission divided registered partnerships schemes into the two categories of "marriage-minus" and "blank-slate-plus." *Id.*

[187] BEYOND CONJUGALITY, *supra* note 145, at 29-37.

[188] *Id.* at 29.

[189] *Id.* at 29-37.

> relationships do matter, a preferred option is to allow individuals to identify the relationships most important to them. If that option is not workable, then consideration needs to be given to revising legal definitions to more accurately capture relationships that have characteristics relevant to the state objectives at issue.[190]

The ultimate goal of this methodology is to identify which legal mechanism—registration or ascription—would provide adequate legal protections and benefits for kinship relationships. Along these lines, a registration model could allow parties "to identify the relationships most important to them."[191]

Currently in the United States, laws establishing civil unions, domestic partnership registration and domestic partnership benefits allow conjugal couples to opt into arrangements that provide different levels of legal recognition of their relationships.[192] Likewise, civil union and domestic partnership laws in other countries serve similar functions.[193]

In addition, ascription is another statutory mechanism for recognizing kinship relationships. As with conjugal relationships, this process would provide legal recognition to persons in kinship relationships "without their having taken any positive action to be legally recognized."[194] The problem, however, with granting rights by ascription is that it would treat all similarly situated parties the same without distinction based on the actual arrangements of the parties involved.[195]

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[190] *Id.* at 36-37.

[191] *Id.*

[192] Duncan, *supra* note 172, at 987-88. Related to this is the private recognition of these relationships amongst companies that provide domestic partnership benefits. *Id.* at 965-78.

[193] INT'L GAY & LESBIAN HUMAN RIGHTS COMM'N, INTERNATIONAL: GLOBAL SUMMARY OF REGISTERED PARTNERSHIP, DOMESTIC PARTNERSHIP, AND MARRIAGE LAW (Nov. 2003), http://www.iglhrc.org/cgi-bin/iowa/article/takeaction/resourcecenter/815.html (last visited Nov. 15, 2008). Just over twenty nations sanction civil unions or domestic partnerships in all or part of their jurisdictions. *Id.*

[194] BEYOND CONJUGALITY, *supra* note 145, at 116.

[195] *Id.*

3. Kinship Arrangements: The Next Frontier

The legal recognition and status of marriage relationships has provided many social and economic benefits that are viewed to be the cornerstone of society. To limit those rights, in a changing society, to married heterosexual individuals circumscribes the ability of individuals to create and maintain viable social and economic relationships outside of marriage. As a starting point, domestic partnership law and reciprocal beneficiaries law provide a basic set of rights and obligations primarily for conjugal couples. Similarly partnership benefit arrangements allow the sharing of limited legal protections. The Canada Law Commission approach creates the methodology that should be employed to examine, revise and repeal existing laws and to adopt new laws and policies to support kinship relationships. Accordingly, approaches to kinship legislation should employ current models while examining how laws can better support economic and emotional relationships that serve societal goals.

VI. CONCLUSION

> Think about how it feels to be a target—a target of stares, a target of scorn, a target of spite. Think about how bias and hate continue to live underground, where they have grown deep and varied roots. Think about the pain when hate breaks the surface. Think about bias attacking your family. Think about another's ignorance holding back someone you love, keeping them from living up to their potential, from contributing their talents, from building our communities.
>
> . . . .
>
> We, as a society, stand today at a moment when progress and decline, opportunity and hopelessness, are in desperate conflict.[196]

Therein lies the *paradox of oppression*. Oppression,

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[196] Senator Stan Rosenberg, Our Best Angels, Presented to Unitarian Universalist Society of Amherst (Jan. 12, 1997).

discrimination and disenfranchisement in its endless forms must concern all of us. In his seminal work, *Pedagogy of the Oppressed*, Paulo Freire observed, "[a]s the oppressors dehumanize others and violate their rights, they themselves also become dehumanized. As the oppressed, fighting to be human, take away the oppressors' power to dominate and suppress, they restore to the oppressors the humanity they had lost in the exercise of oppression."[197] Dehumanization is a distortion of what it means to be fully human.[198] Indeed, we are at a crossroad of challenge and of opportunity to preserve our humanness, our kinship families in all of their forms, our children and generations beyond. There is a rich tapestry of stories woven in the souls of survivors and those who did not. However, we must not settle for mere *survival.* The *only* standard is to fully give ALL children and ALL families what they need to grow and thrive.[199]

Instead of focusing on the results of a break-down of the kinship family, attention should focus on society as a whole recognizing these family units. Data confirms that kinship families would be more productive and enhance our collective lives. If those within a kinship unit would give thoughtful consideration of what the family needed prior to entering an agreement, many break downs would be avoided. Many of the psychological/social problems would be solved if states validated kinship families. As the Law Commission of Canada concluded:

> The state has a role in providing a legal framework to help people fulfill the responsibilities and rights that arise in close personal relationships. However, any involvement by the state should honour the choices that people make. Instead of focusing mainly on married couples and couples deemed to be "marriage-like," governments should establish registration schemes to facilitate the private ordering of both conjugal and

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[197] PAULO FREIRE, PEDAGOGY OF THE OPPRESSED 42 (Myra Bergman Ramos trans., 1970); *see also* DOMAN LUM, CULTURALLY COMPETENT PRACTICE: A FRAMEWORK FOR UNDERSTANDING DIVERSE GROUPS AND JUSTICE ISSUES 55, 60-63 (2007).

[198] Lum, *supra* note 197, at 56.

[199] *See generally* Nancie Palmer, *Fostering Resiliency in Children: Lessons Learned in Transcending Adversity*, 19 J. SOC. THOUGHT 69, 85 (1999).

non-conjugal relationships.[200]

[200] BEYOND CONJUGALITY, *supra* note 145, at 131. Regrettably, the Law Commission of Canada was closed at the end of 2006 after the conservative Harper government cut all of its funding. John Ibbitson, *Fatal Cuts to Law Panel Deeply Ideological*, GLOBE & MAIL (CAN.), Sept. 28, 2006, at A4. Shortly thereafter, the Ontario government formed its own Law Commission. Kirk Makin, *Ontario Unveils Law-Reform Commission*, GLOBE & MAIL (CAN.), Dec. 1, 2006, at A6.

LEARNING NEUROSCIENCE THE HARD WAY: THE TERRI SCHIAVO CASE AND THE ETHICS OF EFFECTIVE REPRESENTATION

Robert A. Destro[*†]

"It has been said innumerable times, and I have also repeated it, that 'facts remain and theories pass away . . . To observe without thinking is as dangerous as to think without observing.'"[1]

"These results confirm that, despite fulfilling the clinical criteria for a diagnosis of vegetative state, this patient retained the ability to understand spoken commands and to respond to

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* Professor of Law & Director, Interdisciplinary Program in Law & Religion, Columbus School of Law, The Catholic University of America. Parts of this article are revised and rewritten from Charles A. Erin & Suzanne Ost, eds., THE CRIMINAL JUSTICE SYSTEM AND HEALTH CARE (Oxford University Press 2007): Chapter 8, Robert A. Destro, *Lessons in Legal and Judicial Ethics from Schiavo: The Special Responsibilities of Lawyers and Judges in Cases Involving Persons with Severe Cognitive Disabilities*, and are used by permission of Oxford University Press. I would like to thank Dr. Erin and Dr. Ost for inviting me to contribute to that volume. That invitation encouraged me to collect many of the thoughts and observations developed during my involvement in the *Schiavo* case from August 2004 through March 2005. I also thank Oxford University Press (www.oup.com), which has granted "Free permission Author's own material" for the material that appears in the Erin & Ost volume. Additional acknowledgments appear in the endnote on page 903.

[1] Alvaro Fernandez, Comment, *Santiago Ramon y Cajal: Recollections of My* Life, SHARP BRAINS, Aug. 31, 2008, http://www.sharpbrains.com/blog/2008/08/31/santiago-ramon-y-cajal-recollections-of-my-life/ (quoting SANTIAGO RAMON Y CAJAL, RECOLLECTIONS OF MY LIFE 638 (E. Horne Craigie & Juan Cano trans., First MIT Press 3d ed. 1996).

them through her brain activity, rather than through speech or movement."[2]

In re Guardianship of Schiavo[3] is one of the most notable, complex, and cautionary controversies in American legal and political history. It began in the early 1990s when Terri Schiavo suffered a massive brain injury after a cardio-respiratory failure of indeterminate origin. It ended when she died from marked dehydration[4] after a Florida court ordered her guardian to remove her feeding tubes and to withhold all further nutrition and hydration. The political power struggle it ignited between the Florida and federal courts and the elected branches of the Florida and federal governments held the nation and the world transfixed for weeks.

The recent case of Eluana Englaro, described by one commentator as "[t]he Complicated Case of [the] 'Italian Terri Schiavo,"'[5] has had an equally unsettling effect on the Italian people and their government. Eluana's case began when she suffered a traumatic brain injury (TBI) in a 1992 automobile accident. It ended in March 2009, when an Italian court

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[2] Adrian M. Owen et al., *Detecting Awareness in the Vegetative State*, 313 SCI. 1402 (Sept. 8, 2006).

[3] *In Re* Guardianship of Schiavo, 780 So. 2d 176, 177 (Fla. Dist. Ct. App. 2001), *aff'd without opinion*, 789 So. 2d 348 (Fla. 2001).

[4] JON R. THOGMARTIN, M.D. ET AL., REPORT OF AUTOPSY: THERESA SCHIAVO, CASE NO. 5050439 (June 13, 2005), at 8, Question 7 ("By what mechanism did Theresa Schiavo die?"). Because the Medical Examiner could not determine the cause of the "severe anoxic brain injury . . . with reasonable medical certainty[, the] manner of death will therefore be certified as undetermined." *Id.* at 9, Question 8 ("What was the cause and manner of death?").

[5] *See, e.g.*, Peter Parisius, *The Complicated Case of "Italian Terri Schiavo,"* THE ITALY DISPATCH, Dec. 25, 2008, *available at* http://italydispatch.splinder.com/post/19415896/The+complicated+case+of+%22Itali. *See also* Gina Doggett, *Uproar in Italy Over Mercy Killing*, SUNDAY TELEGRAPH (Sydney, Australia), Feb. 8, 2009, *available at* 2009 WLNR 2450460; News International Ltd., *Coma Woman Dies 'According to Her Wish' Before Parliament Can Restore Life Support*, THE TIMES (U.K.), Feb. 10, 2009, *available at* 2009 WLNR 2595132. *Cf.* Benedetta Argentieri, *Eluana, più di diecimila in corteo Appello dalla Cattolica: ora rispetto* [Eluana: More than 10,000 March from the Catholic University of Milan], CORRIERE DELLA SERA (Milan, Italy), Feb. 8, 2009, at 9, *available at* 2009 WLNR 2471340 (reporting that Italian Undersecretary of Health, Eugenia Roccella, sought to assure the crowd that "The Englaro case is not this country's Terri Schiavo case.").

authorized her father to withhold nutrition and hydration. Based on the press accounts of the case to date, it is safe to assume that her case will shape the thinking of Italians on these issues for many years to come.

At last count, over 17,000 English-language articles discuss the legal, medical, political, medical ethics, and cultural dimensions of the *Schiavo* case.[6] Only a few discuss the bewildering complexity of its facts, or seek to place them in the scientific, medical, or cultural context of the 1990s in which the Schiavo and Englaro cases arose. *None* of them discuss the ethical obligations of the lawyers and judges whose professional obligations serve as the protections-of-last-resort for the interests and human dignity of persons whose cognitive abilities have been impaired or destroyed by disease, stroke, or a traumatic brain injury (TBI).[7]

This article seeks to fill that void by looking at some of the lessons that can be learned from a critical examination of the *Schiavo* case through the lens of legal ethics. This is a subject on which I can claim some unique knowledge. In *Schiavo v. Bush*,[8] I argued the case for the constitutionality of the executive review process established by the Florida legislature after Judge

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[6] A full-text search on the phrase "Terri Schiavo" in Academic Search Premier produced 17,738 English language references. Of this number, 9,043 appeared in academic journals, including some law reviews. A Westlaw search on the same phrase returned 525 references in law reviews and legal periodicals, and a LEXIS search of law reviews, legal periodicals, and CLE materials produced 369. This is understandable. The case fits comfortably within the intersecting boundaries of civil and criminal procedure; the law of homicide; family, guardianship, and disability law; the art and science of medicine; neuroscience; professional ethics; constitutional law; politics; and morals.

[7] A full-text search on the phrase "Terri Schiavo" & "Rule 1.14" produced five references in LEXIS and eight in Westlaw. Most of these dealt with issues of disability and incompetence in the context of estate planning. *See, e.g.*, Michael D. Toobin, *Considerations in Planning for Incapacity*, NATIONAL BUSINESS INSTITUTE: ESTATE PLANNING BASICS (2008), *available at* 42293 NBI-CLE 99. The only article that came close to addressing this topic was that of Professor Pamela Champine. *See* Pamela Champine, *Expertise and Instinct in the Assessment of Testamentary Capacity*, 51 VILL. L. REV. 25, 26 (2006) (comparing the problem facing courts that must decide whether a testator lacks mental capacity to the situation in which the "fallibility of medical expertise requires individuals to exercise judgment about when to trust their own instincts and when to rely on professional medical advice").

[8] Bush v. Schiavo, 885 So. 2d 321 (Fla. 2004), *cert. denied*, 543 U.S. 1121 (2005).

Greer's September 17, 2003, order that Terri Schiavo's feeding tube be withdrawn.[9] "Terri's Law"[10] authorized Governor Jeb Bush to issue a stay of execution of the probate court's order, and to seek the appointment of a court-appointed guardian *ad litem* who would to review the record in the proceedings before Judge Greer and report back to the Governor and the court.[11] That stay was embodied in an October 2003 Executive Order to sustain Terri Schiavo's life during the pendency of the review process.[12] I later served as co-counsel on the legal team representing the Schindler family, and wrote the initial justification for a proposed amendment to the federal habeas corpus statute[13] that would have given Terri access to the great writ. Public Law 109-3 emerged from that process.[14]

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[9] *See infra text accompanying* note 131.

[10] 2003 Fla. Laws 418, *available at* http://laws.flrules.org/files/Ch_2003-418.pdf.

[11] The Florida Supreme Court heard oral arguments in *Bush v. Schiavo* on August 31, 2004. The transcript of the oral argument is available at http://www.wfsu.org/gavel2gavel/transcript/04-925.htm. The video is available at http://www.wfsu.org/gavel2gavel/archives/04-08.html. My co-counsel in the case, Kenneth J. Connor, Esq., argued the proposition that neither the passage of Terri's Law, nor the Governor's assertion of protective custody, violated the terms of Judge Greer's September 17, 2003, order.

[12] Fla. Exec. Order No. 03-201 (Oct. 21, 2003), *available at* http://news.findlaw.com/hdocs/docs/schiavo/flagovexord03201.html. Given the interests at stake, the only way to accomplish that end was to insert a new nutrition and hydration tube.

[13] 28 U.S.C. § 2254(a) (2007). The goal of that amendment would have been to make it clear that persons in Terri's situation were persons "in custody." *See, e.g.*, Memorandum of March 6, 2005 from Robert A. Destro to Brian Darling, "Proposed *Habeas* Amendments regarding Terri Schiavo case" at 1 ¶3 (on file with author) ("In sum, if Terri Schiavo's case is not appropriate for habeas corpus, it is hard to figure out what cases might be. Ted Bundy got better process than she did.").

[14] Relief of the Parents of Theresa Marie Schiavo, Pub. L. No. 109-3, 119 Stat. 15 (2005). The legislative saga is just as interesting as the history of the intra-family dispute that sparked this litigation, the history of the litigation itself, and the history of the tantalizing, but ultimately unsuccessful, last-ditch efforts to have Terri Schiavo's consciousness disorder evaluated by two of the world's leading experts in the field. Space limitations and relevancy concerns make it impossible to recount that story here, but it is a story worth telling, especially the part that deals with the extensive negotiations held between the House of Representatives and the Senate that led to the framing of Public Law Number 109-3 as a special bill for the relief of Terri Schiavo's family rather than a one-line amendment to the habeas corpus statute. Pub L. No. 109-3.

Based on those experiences and continuing concerns about the welfare and effective representation of those suffering disease or trauma-induced brain injury, I will argue here that the criminal justice process provides an excellent reference point by which to judge the adequacy of the *civil* justice process in cases where severely incapacitated persons are alleged to be in need of medical or rehabilitation services. Had Theresa Marie Schindler Schiavo (commonly known as "Terri") been a criminal facing either the death penalty or a term of incarceration in any state or federal court in the United States, the ethical and legal norms built into the process by which criminal charges are proved, defended, and appealed would have required the federal appellate courts to order the State of Florida to conduct a new trial in strict conformity to the civil guardianship and medical neglect process mandated by Florida and federal law.

Part I looks at the three main "narratives" that are commonly employed to describe the *Schiavo* case, and it recounts the basic facts concerning Terri Schiavo's brain injury and the early, but quickly-abandoned, attempt at rehabilitation. Part II is an examination of how the demise of one of the most profoundly harmful dogmas in the history of medicine—the theory that the brain is "hard-wired" and that no amount of rehabilitation can cause the brain to rewire itself—occurred too late in the litigation for the judges or advocates in either *Schiavo* or *Englaro* to understand that Terri and Eluana *might* actually have been able to communicate "cognitively" rather than physically. That too is a cautionary tale about the ways in which "iconoclastic researchers" were able to use state-of-the-art diagnostic imaging and aggressive, but (then) unorthodox, rehabilitation techniques to demonstrate that conventional wisdom in neurology in the 1990s was simply wrong. Part III develops a model of ethical and effective representation and judging brain injury cases, and Parts IV through VII draw lessons from that model based on the facts of the *Schiavo* case.

I. WHAT HAPPENED TO TERRI SCHIAVO? A TALE OF FOUR NARRATIVES

Exploring the legal and ethical reasons why the civil justice

system failed so badly in the *Schiavo* case is not easy. At the beginning of this article, I described the Schiavo case as "notable, complex, and cautionary." Most commentators agree, but their understanding of the facts leads them to utilize three very different narratives in their telling of the story.[15] In this section, I will discuss each of these narratives in detail, but will begin with a common point of reference: the facts that appear in the trial and appellate records of the *Schiavo* case. For present purposes, this is the fourth, or "Transcript Narrative." The other three are the "Death with Dignity" narrative, the "Killing Terri Schiavo" narrative, and the "Judicial Independence" narrative.

A. The "Transcript" Narrative

1. The Medical Case and Initial Court Proceedings

The medical facts of the *Schiavo* case are fairly straightforward. Sometime before 5:00 a.m. on February 25, 1990, Theresa Marie ("Terri") Schindler Schiavo, then twenty-six years old, suffered cardio-respiratory arrest.[16] According to

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[15] The importance of characterization cannot be understated. One goal of this article is to explain why the *Schiavo* case is an excellent example of the dangers that arise for both law and medicine when policy disputes are resolved through a process of "characterization," rather than a careful analysis of the facts and an equally careful balancing of the relevant interests involved. Kathleen Sullivan describes the difference between the two approaches as follows:

> Categorization and balancing each employ quite different rhetoric. Categorization is the taxonomist's style—a job of classification and labeling. When categorical formulas operate, all the important work in litigation is done at the outset. Once the relevant right and mode of infringement have been described, the outcome follows, without any explicit judicial balancing of the claimed right against the government's justification for the infringement. Balancing is more like grocer's work (or Justice's)—the judge's job is to place competing rights and interests on a scale and weigh them against each other. Here the outcome is not determined at the outset, but depends on the relative strength of a multitude of factors. These two styles have competed endlessly in contemporary constitutional law; neither has ever entirely eclipsed the other.

Kathleen M. Sullivan, *Post-Liberal Judging: The Roles of Categorization and Balancing*, 63 U. COLO. L. REV. 293-94 (1992).

[16] JON R. THOGMARTIN, M.D. et al., REPORT OF AUTOPSY: THERESA SCHIAVO, CASE NO. 5050439 at 2 (June 13, 2005), *available at*

court and medical examiner documents, her husband, Michael Schiavo, found her lying face-down on the floor at 5:00 a.m. He placed a call to Terri's father, Robert Schindler, at around 5:40 a.m. Mr. Schindler told him to hang up and call for emergency medical assistance. According to logs kept by the St. Petersburg, Florida, police, the emergency call was received at 5:40 a.m. Emergency medical services personnel arrived approximately twelve minutes later (at 5:52 a.m.) and began resuscitation immediately. According to the Report of the Pinellas County Medical Examiner: "[a]lthough a pulse was documented at 06:32hrs, a measurable systolic blood pressure was not recorded until 0646hrs[,] almost one hour after resuscitation began."[17] The result was a massive brain injury.[18] Intensive rehabilitation efforts and the first set of legal proceedings—medical malpractice cases against her primary care physician and the gynecologist who had been treating her for infertility—began shortly thereafter.

2. The Guardianship Case

At the root of the legal case was an intra-familial dispute over the nature, quality, and extent of the rehabilitation and medical care provided to Terri Schiavo after she was released from the hospital. Because Terri had left no advance directive of any kind, her husband, Michael Schiavo, became her legal guardian by operation of Florida law.[19] Her parents, Robert and Mary Schindler, believed Mr. Schiavo to be unfit to serve as guardian, and mounted several unsuccessful attempts to have the court remove him so that they could assert their right as parents under Florida law to undertake the guardianship role themselves.

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www.sptimes.com/2005/06/15/schiavoreport.pdf, at 29.

[17] The post-mortem examination of Mrs. Schiavo showed "marked, global anoxic, ischemic encephalopathy resulting in massive cerebral atrophy," but was unable to draw any conclusions concerning the condition and function of her brain at any point during her life post-trauma. *See id.* at 9; www.sptimes.com/2005/06/15/schiavoreport.pdf, at 35 (Questions 5-7).

[18] *Id.* at 8.

[19] FLA. STAT. §§ 765.401, 744.312 (2007).

Review of the extensive, verbatim trial record developed over more than fifteen years discloses that there were significant, and unresolved, disputes between Terri's husband and her parents over brain function, including visual and auditory abilities, and the physical response of her brain to various forms of stimulation.[20] These disputes led to an ongoing battle over the value of rehabilitation, basic medical care, and routine forms of physical and mental stimulation such as listening to music and trips outdoors.[21] They eventually led to complaints by Terri's parents that Michael had abandoned her, first by refusing to continue rehabilitation, and later, through his relationship with other women, including one with whom he had two children.[22]

Money also played a role in this dispute. The medical malpractice case against the gynecologist resulted in a 1993

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[20] *See generally* Transcript of Record at Vol. IV, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Oct. 15-17, 20, 22, 2002).

[21] *See infra* text accompanying note 29.

[22] Second Amended Petition to Remove Guardian at 3-8, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Jan. 10, 2005). Ironically, the Schindler family might have been more successful in their attempts to remove Michael Schiavo as guardian had they petitioned the guardianship court for a divorce. In 1994, the Fifth District Court of Appeals held that Florida's no-fault divorce law allows for dissolution proceedings to be filed against the competent spouse on behalf of the ward. Vaughan v. Guardianship of Vaughan, 648 So. 2d 193 (Fla. Dist. Ct. App. 1994). Although the majority view is that a guardian or conservator needs express statutory authority to commence a dissolution action on behalf of the ward, *see* Murray v. Murray, 426 S.E.2d 781 (S.C. 1993); *In re* Marriage of Drews, 503 N.E.2d 339 (Ill. 1986), *cert. denied*, Drews v. Drews, 483 U.S. 1001 (1987), courts in other states began to accept the proposition that the best interests of the ward may sometimes require the initiation of divorce proceedings. *See, e.g.*, Ruvalcaba v. Ruvalcaba, 850 P.2d 674, 683-84 (Ariz. Ct. App. 1993) (holding that a guardian may bring a dissolution action on behalf of the incapacitated ward pursuant to his general powers to act on the ward's behalf); Smith v. Smith, 335 N.W.2d 657 (Mich. Ct. App. 1983) (holding that guardian of incompetent person can file divorce action against competent spouse); Nelson v. Nelson, 878 P.2d 335, 341 (N.M. Ct. App. 1994) ("[A] guardian of an adult incompetent ward may initiate divorce proceedings on behalf of the ward."); Broach v. Broach, 895 N.E.2d 640 (Ohio Ct. App. 2008); Kronberg v. Kronberg, 623 A.2d 806, 810 (N.J. Super. Ct. Ch. Div. 1993) (holding a guardian *ad litem* has the authority to obtain a divorce on behalf of an incompetent person); Stubbs v. Ortega, 977 S.W.2d 718, 724 (Tex. Ct. App. 1998) ("Texas public policy does not prohibit authorizing a guardian to petition for divorce on behalf of her mentally incapacitated ward.").

award of $750,000 in economic damages[23] to Terri Schiavo, and $300,000 in damages for loss of consortium and non-economic damages to Michael,[24] who had testified in 1992 that his incapacitated wife was expected to live out her normal life span and that he would provide for her health care.[25] By early 1994, however, his position had changed. When Terri developed a urinary tract infection, he elected not to treat it and requested a "Do Not Resuscitate" order in the event she suffered another cardiac arrest.[26] When the nursing facility resisted the order, he cancelled it and transferred her to another facility.[27] In 2000, Michael transferred Terri (who was not terminally ill) to the hospice in which she spent the last five years of her life.[28] From that point forward, her parents alleged, he would not permit routine medical or dental care, or any form of physical stimulation, including physical therapy or rehabilitation, the

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[23] Jay Wolfson, Guardian *Ad Litem* for Theresa Marie Schiavo, A REPORT TO GOVERNOR JEB BUSH AND THE SIXTH JUDICIAL CIRCUIT IN THE MATTER OF THERESA MARIE SCHIAVO 9 (Dec. 1, 2003), *available at* http://abstractappeal.com/schiavo/WolfsonReport.pdf.

[24] *Id.* at 9; *see also In re* Guardianship of Schiavo, 780 So. 2d 176, 177-78 (Fla. Dist. Ct. App. 2001) [hereinafter *Schiavo I*].

[25] Direct testimony of Michael Schiavo, Transcript of Record, Barnett Bank Trust Company as Guardian of the Property of Theresa Schiavo and Michael Schiavo, Individually v. G. Stephen Igel, M.D., No. 92-939-15 (November 5, 1992) at p. 26, line 25 through p. 28, line 4 [hereafter "Medical Malpractice Case"]. *See also*, Jurisdiction Brief of Petitioners, Schindler v. Schiavo, 855 So. 2d 621 (Fla. 2003) (No. SC03-1242), 2003 WL 22400860, at *1.

[26] Wolfson, *supra* note 23, at 10. Depending on its severity, an untreated urinary tract infection (UTI) can lead to acute renal failure. *See* U.S. National Library of Medicine & National Institutes of Health, *Kidney Infection*, MEDLINEPLUS MEDICAL ENCYCLOPEDIA, *available* at http://www.nlm.nih.gov/medlineplus/ency/article/000522.htm#Expectations%20(prognosis) (last accessed March 9, 2009); *id.* ("Acute Renal Failure – Prognosis.") *available at* http://www.nlm.nih.gov/medlineplus/ency/article/000501.htm#Expectations%20(prognosis) (last accessed March 9, 2009).

[27] Wolfson, *supra* note 23, at 10.

[28] *See* Second Amended Petition to Remove Guardian at 15-16, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Jan. 10, 2005). Terri Schiavo did not have a "terminal condition." Federal rules governing reimbursement for hospice care limit allowable reimbursement to periods for which the physician "must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course." *See* 42 C.F.R. § 418.22(b)(1) (Certification of terminal illness); 42 C.F.R. § 418.21 (Duration of hospice care coverage—Election periods).

use of a wheelchair to take her outside, natural light from the window, or music in her room.[29] As we shall see in the next section, that lack of stimulation guaranteed a downward spiral in both the physical condition of her brain and a reduction in whatever amount of cognitive ability she had.[30]

All of these factors led the Florida District Court of Appeal to recognize that "both Michael and the Schindlers [were] suspicious that the other party [was] assessing Theresa's wishes based upon their own monetary self-interest,"[31] but that it saw "no evidence in this record that either Michael or the Schindlers seek monetary gain from their actions. [They] simply cannot agree on what decision Theresa would make today if she were able to assess her own condition and make her own decision."[32] The district court did hold, however, that Michael could not be

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[29] *See* Second Amended Petition to Remove Guardian at 17-21, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Jan. 10, 2005).

[30] It was known as early as 1994 that music has a discernable effect on the brain that can be measured by neuroimaging technologies such as positron emission tomography (PET scanning) and functional magnetic resonance imaging (*f*MRI). *See* K. Vlad Hachinski & Vladimir Hachinski, *Music and the Brain*, 151 CAN. MED. ASS'N J. 293, 295 (1994) (noting that "PET can now be used to ascertain areas of brain stimulation during auditory processing" and that "[p]atients subjected to musical stimuli displayed activity in the frontotemporal areas of the brain"). *Accord* Annirudh D. Patel, *Language, Music, Syntax, and the Brain*, 6 NATURE NEUROSCIENCE 674, 679 (July 2003) (proposing the "hypothesis that linguistic and musical syntax share certain syntactic processes (instantiated in overlapping frontal brain areas) that apply over different domain-specific syntactic representations in posterior brain regions"). The post-mortem examination of Terri Schiavo's brain showed "relative preservation of the frontal and temporal lobes"—areas that could have been scanned in an attempt to ascertain some of her cognitive abilities. *See* Letter from Stephen J. Nelson, Chief Medical Examiner, 10th Judicial Circuit of Florida, to Jon R. Thogmartin, District 6 Medical Examiner 4 (June 8, 2005) (Neuropathology Report) in THOGMARTIN, *supra* note 4 at 15.

[31] *In re* Guardianship of Schiavo, 780 So. 2d 176, 178 (Fla. Dist. Ct. App. 2001). The court further explained as follows:

> This lawsuit is affected by an earlier lawsuit. In the early 1990s, Michael Schiavo, as Theresa's guardian, filed a medical malpractice lawsuit. That case resulted in a sizable award of money for Theresa. This fund remains sufficient to care for Theresa for many years. If she were to die today, her husband would inherit the money under the laws of intestacy. If Michael eventually divorced Theresa in order to have a more normal family life, the fund remaining at the end of Theresa's life would presumably go to her parents.

Id.

[32] *Id.*

permitted to make the decision to continue or refuse life-sustaining treatment by stating as follows:[33]

> Because Michael Schiavo and the Schindlers could not agree on the proper decision and the inheritance issue created the appearance of conflict, [the Court of Appeal permitted] Michael Schiavo, as the guardian of Theresa, to invoke[ ] the trial court's jurisdiction to allow the trial court to serve as the surrogate decision-maker.[34]

As we shall see in the discussion below, it is my contention that this ruling was legally and ethically erroneous on several grounds,[35] and that it tainted the fact-finding process to the point where it became necessary to argue that Terri Schiavo was denied the rudiments of due process in the guardianship.

B. The "Public Narratives"

1. The "Death with Dignity" Narrative[36]

The first of the "public narratives" is told from the perspective of Michael Schiavo, Terri Schiavo's husband. In Michael Schiavo's version of the story, Terri was "brain dead"[37] when the litigation began, and his efforts to seek an end to

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[33] *Id.* In light of the finding that there was an appearance of conflict of interest, this holding was required by the conflict of interest provisions of Florida's guardianship statute. FLA. STAT. § 744.309(3) (2009).

[34] *In re* Guardianship of Schiavo, 780 So. 2d at 178.

[35] The Court of Appeal was correct in its view that Florida law does not automatically compel the appointment of a guardian *ad litem* when a surrogate decision-maker may ultimately inherit from the patient, because it recognized that "there may be occasions when an inheritance could be a reason to question a surrogate's ability to make an objective decision." *Id.* Its mistake, discussed below in Part VI(D), was that Florida law expressly forbids the appointment of a guardian who has a potential conflict of interest.

[36] *See, e.g.,* Leslie Pickering Francis, *(Mis)framing Schiavo as Discrimination Against Persons with Disabilities*, 61 U. MIAMI L. REV. 789 (2007).

[37] *See, e.g.,* Richard Luscombe, *Bush Defied in Right-to-Die Case,* THE GUARDIAN (London, UK), Mar. 23, 2006, *available at* http://www.guardian.co.uk/world/2005/mar/23/richardluscombe ("The Schindlers say their daughter is responsive and could improve with treatment, but her husband, Michael Schiavo, claims she is brain dead . . . .").

further nutrition and hydration was "not merely . . . [a fight] for what he thought was right, but also for what he claimed Terri wanted for herself."[38]

The medical testimony presented on Michael's behalf supports the guardianship court's finding that Terri Schiavo was in a persistent vegetative state[39] throughout the course of the guardianship. Three witnesses testified that Terri Schiavo had made four oral statements to the effect that she would not want to be kept alive by artificial means were she to become incapacitated. Her husband, Michael, testified that Terri had stated that she did not want to be a burden on her family or "live like that."[40] Michael's brother, Scott Schiavo, testified that Terri had told him that she did not "want to be kept alive on a machine,"[41] and Michael's sister-in-law, Joan Schiavo, testified

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[38] Alan Meisel, *Suppose the Schindlers Had Won the Schiavo Case*, 61 U. MIAMI L. REV. 733, 733-34 (2007). The author went on to state as follows:

> But Michael Schiavo claimed not merely to be fighting for what he thought was right, but also for what he claimed Terri wanted for herself. His position was that it was not a vindication of his interests that he sought, but hers. And he was fighting not only for Terri, but for a principle—that the wishes of patients who are unable (and never will be able) to speak for themselves be respected. This being the case, giving in to the Schindlers was not having his cake and eating it, too. It was not even a compromise. It was a sellout: a betrayal of Terri and a betrayal of a principle.

Id. at 734.

[39] *See, e.g.*, Brad Smith, *Schiavo Videotapes Offer Powerful But Misleading Evidence*, TAMPA TRIBUNE, Mar. 20, 2005, at 12, *available at* http://news.tbo.com/news/MGBQ67CTI6E.html ("[Videotapes taken at the nursing home] more accurately show the Pinellas Park woman, argue some doctors and Michael Schiavo, who says his wife is brain-dead and should die in dignity after 15 years[,] in what doctors term a persistent vegetative state.").

[40] *Money, Fear and Prejudice: Why the Courts Killed Terri Schiavo,* 30 WOMEN'S RTS. L. REP. 42, 84 (2008) (quoting Transcript of Trial at 31-31, 33, *In re* Guardianship of Schiavo, No. 90-2908GC-003 (Fla Cir. Ct. Apr. 17, 2000)). Professor Patricia Norwood Harris provides the "alleged oral statements by Terri and their context . . . as follows":

> #1. If [she] "ever had to be a burden to anybody like [her uncle was to her grandmother], [she didn't] want to live like that." [Allegedly said to Michael Schiavo during a train ride.]
>
> #2. Do not "keep [me] alive on anything artificial." [Allegedly said to Michael Schiavo while watching a documentary.]

Id.

[41] *Id.* (quoting Excerpts of Trial at 15, *In re* Guardianship of Schiavo, No. 90-2908GC-003 (Fla. Cir. Ct. Apr. 17, 2000)). Professor Harris provides the January 24,

that she and Terri had agreed, after watching a movie "about a guy who had an accident and he was in a comma [sic]," that "we would want it stated in our will we should want the tubes and everything taken out."[42] Based on this evidence, Judge Greer found that Terri Schiavo would have refused further artificial nutrition and hydration.

It is that finding that leads most commentators to accept the "right to die" narrative, and to assert that the *Schiavo* case is legally significant because the Florida and federal judiciaries stood firm for the preservation of the privacy and personal autonomy of persons who, like Terri, had entered a persistent vegetative state without leaving an advance directive.[43] That finding is also politically significant. In some versions of the "death with dignity narrative," the debates in Congress and the Florida Legislature pitted civil libertarians against "vitalists" whose "fundamentally primitive belief[s]" lead them to conclude that "despite the absence of cognition of any sort, a beating heart in a permanently unconscious human needs to be protected the same way as a beating heart in a human who has cognition and sentience."[44]

2000, testimony of Scott Schiavo as follows: "#3. 'If I ever go like that, just let me go. Don't leave me there. I don't want to be kept alive on a machine.' [Allegedly said to Scott Schiavo at a funeral luncheon for Scott's grandmother in February of 1986.]" *Id.*

[42] *Id.* (quoting Excerpts of Trial at 40, *In re* Guardianship of Schiavo, No. 90-2908GD-003 (Fla. Cir. Ct. Feb. 11, 2000)). Professor Harris provides the January 24, 2000, testimony of Joan Schiavo as follows:

> #4. We had watched a movie one time on television. It was about somebody. I don't remember. I don't remember the movie. It was about a guy who had an accident and he was in a comma [sic]. There was no help for him. We had stated that if that ever happened to one of us, in our lifetime, we would not want to go through that. That we would want it stated in our will we should want the tubes and everything taken out." [Allegedly said to Joan Schiavo, who could not remember the date.]

Id.

[43] Bush v. Schiavo, 885 So. 2d 321 (Fla. 2004), *cert. denied*, 543 U.S. 1121 (2005). *See also* Joshua E. Perry, *Biblical Bio-Politics: Judicial Process, Religious Rhetoric, Terri Schiavo and Beyond*, 16 HEALTH MATRIX 553 (2006).

[44] Kenneth Goodman, *Ethics Schmethics: The Schiavo Case and the Culture Wars*, 61 U. MIAMI L. REV. 863, 868 (2007).

2. The "Killing Terri Schiavo" Narrative[45]

This version of the public narrative is told from the perspective of Robert and Mary Schindler, Terri Schiavo's parents. Based on exactly the same trial record, the Schindlers characterized the case as one involving medical and judicial neglect.

The Schindler family disputed the all-important finding[46] that Terri Schiavo was in a "persistent vegetative state" in a variety of ways, including an appearance on *The Oprah Winfrey Show* to present a videotape that, in their view, showed that Terri was at least minimally aware of her surroundings.[47] They countered Michael's evidence with testimony from Terri's mother, Mary Schindler, and Diane Meyer, one of Terri's childhood close friends, that the two of them had discussed with Terri the dispute about termination of life-sustaining measures that had arisen in the highly-publicized case of Karen Ann Quinlan.[48] Based on those conversations, Mrs. Schindler and Ms. Meyer testified that Terri would not, under the circumstances, elect to forego artificial nutrition and hydration.[49] The other Schindler family witness, Jackie Rhodes,

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[45] Michael Stokes Paulsen, *Killing Terri Schiavo*, 22 CONST. COMMENT. 585 (2006) ("But it reduces to this: The State of Florida, acting through its judiciary, ordered a severely disabled woman to be slowly dehydrated and starved to death, by removing her feeding tube.").

[46] *See* FLA. STAT. § 765.305 (2007) ("procedure in the absence of a living will").

[47] Dave Reynolds, *Schindlers Appeal Judge's Efforts To Block Them From Schiavo Suit; Family Takes Case To Oprah Show*, INCLUSION DAILY EXPRESS, Nov. 17, 2003, *available at* http://www.mnddc.org/news/inclusion-daily/2003/11/111703fladvschiavo.htm (noting that "Terri's parents believe that she is alert and responsive and that she might improve with rehabilitative therapies that Mr. Schiavo has denied her for at least the past 10 years.").

[48] *In re* Quinlan, 355 A.2d 647 (1976), *cert denied* 429 US 922 (1976).

[49] O. Carter Snead, *The (Surprising) Truth About Schiavo: A Defeat for the Cause of Autonomy*, 22 CONST. COMMENT. 383, 397-98, 398 n.43 (2005) (quoting Transcript of Record at 372-73, 762, *In re* Guardianship of Schiavo No. 90-2908GD-003 (Fla. Cir. Ct. January 2000)). Direct examinations of Mary Schindler and Diane Meyer, respectively, provided as follows:

> Mary Schindler (Ms. Schiavo's mother) and Diane Meyer (Ms. Schiavo's childhood friend) testified that, based on conversations with Ms. Schiavo about the widely publicized Quinlan case (involving a dispute about termination of life-sustaining measures), they believed that Ms. Schiavo would not, under the

"testified that in the many times she and Ms. Schiavo had visited her grandmother in a nursing home, Ms. Schiavo never expressed to her that she would wish to decline artificial nutrition and hydration were she ever to fall into a profoundly dependent condition."[50] They argued on appeal that the evidence presented by Michael Schiavo and his relatives concerning the choice Terri would have made, had she been capable of doing so, was not "clear and convincing."[51] They also questioned the integrity of the fact-finding process by seeking to have the judge recuse himself[52] and by filing several motions to have Michael Schiavo removed as Terri's guardian.[53]

From the perspective of the Schindler family and their supporters, the "death with dignity" narrative ignored advances in both diagnostic imaging and rehabilitation medicine, and it served as a political cover from what they saw as his desire for Terri "to die so that he can marry another woman with whom he has fathered two children, and so he can benefit from what's left of an insurance settlement that now pays for her treatment."[54] When their efforts to protect their daughter failed in the courts, they sought redress of their grievances from the political branches. To the Schindlers, the order to withhold further nutrition and hydration made the case into the functional equivalent of a death penalty case in which procedural and substantive errors at the trial level render the verdict inherently unreliable.[55]

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circumstances, elect to decline artificial nutrition and hydration.

Id. at 397-98.

[50] *Id.* at 398.

[51] For a complete analysis of the evidence presented by the five witnesses who testified at the trial, *see* Snead, *supra* note 49, at 392-404.

[52] The Motion to Recuse Judge Greer was filed on April 10, 2001, and it was denied. *See* Kathy Cerminara & Kenneth Goodman, *Key Events in the Case of Theresa Marie Schiavo*, UNIVERSITY OF MIAMI ETHICS PROGRAMS: SCHIAVO CASE RESOURCES, *available at* http://www6.miami.edu/ethics/schiavo/timeline.htm (last accessed March 5, 2009). *Id.* at August 10, 2001. There were several attempts to remove Michael Schiavo as guardian. *See* William R. Levesque, Carrie Johnson & Anita Kumar, *Without a Ruling, the Wait Continues*, ST. PETERSBURG TIMES, Mar. 22, 2005, at 1A, *available at* 2005 WLNR 23899652.

[54] *See* Reynolds, *supra* note 47.

[55] Statement of Interest of the United States, Schiavo *ex. rel.* Schindler v. Schiavo,

3. The "Judicial Independence" Narrative

The "judicial independence" narrative pits the fact-finding powers of the courts against the clemency powers of the executive branch. Its focus is on the separation of powers violations that are alleged to have occurred when the Florida Legislature authorized the Governor to stay execution of Judge Greer's order to remove the feeding tube pending a review of the evidence by an independent guardian *ad litem*, and the federalism and civil rights violations that allegedly occurred when Congress and the President approved a bill that permitted *de novo* review of the evidence considered by the Florida courts.

The "Judicial Independence" narrative arises because there is a "true conflict"[56] between the "Death with Dignity" narrative associated with Michael Schiavo, and the "Killing Terri Schiavo" narrative associated with Robert and Mary Schindler, her parents. If, as the Schindlers alleged, Terri Schiavo was a person with a severe cognitive disability who was *not* in "persistent vegetative state" and who would *not* have chosen to forego nutrition and hydration, then a judicial decree ordering that nutrition and hydration be withheld is the functional equivalent of condemning an innocent person to death. In this case, a petition for redress of grievances addressed to the political branches is the only feasible way to get a *de novo* review of the record. If, by contrast, Terri Schiavo *was* in a persistent vegetative state *and* she had stated clearly that she would not have wanted to continue any form of treatment, including nutrition and hydration, Florida law would have made those statements controlling. From this perspective, further litigation or intervention would have been a violation of her rights.

The "judicial independence" narrative thus rests on the two

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358 F. Supp. 2d 1161 (M.D. Fla. 2005).

[56] The term "true conflict" is used to describe a problem in which the interests are irreconcilable. In such a situation, one will, of necessity, be subordinated to the other. When used in the field of choice of law, a finding that there is a "true conflict" requires that the court attempt "a more moderate and restrained interpretation of the policy or interest of one state or the other . . ." in an effort to avoid the conflict. *See* Brainerd Currie, *Comments on Babcock v. Jackson*, 63 COLUM. L. REV. 1233, 1242 (1963).

findings of fact that support the guardianship court's ruling that nutrition and hydration should be withdrawn: 1) that Terri Schiavo was in a persistent vegetative state; and 2) that she would have chosen to refuse further nutrition and hydration rather than continue life in a persistent vegetative state. In this narrative, once those findings are in place, the courts have primary responsibility for ensuring that an incompetent person's "choices" regarding continued treatment are respected. From the judiciary's perspective, any attempt by the Governor or the Legislature to interfere with the execution of the incompetent person's choice to refuse further treatment is a violation of both separation of powers *and* individual rights.

Governor Jeb Bush, by contrast, had his own separation of powers argument. He argued that the executive branch, not the judiciary, is ultimately charged by the Florida and federal constitutions with the protection of the civil rights of individuals whose deaths are ordered, or facilitated, by judicial decree. On this point, he was most certainly correct. In capital cases, it is assumed that the executive branch provides a "check" on the powers of the judiciary. Post-conviction attacks on the integrity of the judicial fact-finding process are routine,[57] and capital defendants and their advocates nearly always seek final review through the Governor's clemency power. This process allows the Governor, or clemency panel, to review the evidence alleged to support the finding of guilt, as well as the integrity of the process in which those findings were made.

House Bill 35-E,[58] dubbed "Terri's Law" by the media, was

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[57] Attacks on the integrity of the fact-finding process are so routine that Congress has taken steps to limit the ability of capital defendants to seek writs of *habeas corpus* from the federal courts. *See* 28 U.S.C. § 2262(c) (2007) (limiting the number of *habeas corpus* petitions that can be filed on behalf of a prisoner sentenced to death).

[58] H.B. 35-E, 105th Leg., Spec. Sess. (Fla. 2003) *available* at http://laws.flrules.org/2003/ch_2003-418.pdf. The substance of the statute provided that:

> (1) The Governor shall have the authority to issue a one-time stay to prevent the withholding of nutrition and hydration from a patient if, as of October 15, 2003:
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> (a) That patient has no written advance directive;
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> (b) The court has found that patient to be in a persistent vegetative state;
>
> (c) That patient has had nutrition and hydration withheld; and
>
> (d) A member of that patient's family has challenged the withholding of

modeled on the executive clemency proceedings employed in Florida capital cases.[59] It gave the Governor post-judgment review powers in cases where the families dispute the findings or the fairness of the proceeding. The Bill's main features included:

(1) Stay of execution[60] pending review of the facts of the case and the fairness of the judicial process by the Governor;[61]
(2) Appointment by the chief judge of the circuit court of an independent guardian *ad litem* whose loyalties are to the ward alone;[62] and
(3) A report to the chief judge and the Governor of the guardian *ad litem's* findings and conclusions,[63] after which the Governor could either dissolve the stay or seek such further relief on behalf of the ward as might be warranted under the circumstances.

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nutrition and hydration.

(2) The Governor's authority to issue the stay expires 15 days after the effective date of this act, and the expiration of that authority does not impact the validity or the effect of any stay issued pursuant to this act. The Governor may lift the stay authorized under this act at any time. A person may not be held civilly liable and is not subject to regulatory or disciplinary sanctions for taking any action to comply with a stay issued by the Governor pursuant to this act.

(3) Upon the issuance of a stay, the chief judge of the circuit court shall appoint a guardian ad litem for the patient to make recommendations to the Governor and the court.

Id.

[59] *Compare* FLA. CONST. art. IV, §8 (Clemency), *with* 2003 Fla. Laws 418.

[60] *Compare* FLA. STAT. § 922.06 (Stay of Execution of Death Sentence) *with* 2003 Fla. Laws 418, at §§ 1-2 (authorizing Governor to issue a temporary stay order ensuring continued nutrition and hydration).

[61] *Cf.* FLA. STAT. § 940.03 (2007) (an application for executive clemency "may require the submission of a certified copy of the applicant's indictment or information, the judgment adjudicating the applicant to be guilty, and the sentence, if sentence has been imposed, and may also require the applicant to send a copy of the application to the judge and prosecuting attorney of the court in which the applicant was convicted, notifying them of the applicant's intent to apply for executive clemency.").

[62] *Compare* FLA. R. CRIM. P. 3.851(b) ("Appointment of Post-Conviction Counsel") *with* FLA. STAT. § 27.703 (specific conflicts of interest).

[63] *Compare* FLA. CONST. art. IV, §8(a) (clemency requires approval of two members of the cabinet), *with* 2003 Fla. Laws 418 §3 (providing for a report to the Governor and the court by the guardian *ad litem*).

When the Governor entered the stay authorized by the statute,[64] the stage was set for the confrontation between the political branches and the courts that marked the final chapters of the *Schiavo* case. When the Florida Supreme Court held, in *Schiavo v. Bush*,[65] that Terri's Law was unconstitutional, the Schindler family's only recourse was to seek a writ of *habeas corpus* from the federal courts.

II. THE MEDICAL CONTEXT

Since most of the commentary characterizes the *Schiavo* case as one involving "the right to die," most articles dealing with the case actually engage the debate over the correctness of the Florida courts' decision that Terri should be "allowed to die" from the marked dehydration that occurs when a PEG (feeding) tube is withdrawn. This article does not address that topic directly. Nor, in my view, should it.

A lawyer who accepts the duty of representing a client understands that "representation . . . , including representation by appointment, does not constitute an endorsement of the client's political, economic, social or moral views or activities."[66] The American Bar Association's ("ABA") Model Rules also assume that the lawyer can maintain enough distance from the facts to maintain "independent professional judgment."[67] In cases where one's *client* is a person who has suffered a severe brain injury, the obvious reference point is Rule 1.14 of the ABA Model Rules, which provides, in relevant part:

> (b) When the lawyer reasonably believes that the client has diminished capacity, is at risk of substantial physical, financial or other harm unless action is taken and cannot adequately act in the client's own interest, the lawyer may take reasonably

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[64] *See* Fla. Exec. Order No. 03-201 (Oct. 21, 2003), *available at*: http://news.findlaw.com/hdocs/docs/schiavo/flagovexord03201.html (last accessed March 4, 2009).

[65] Bush v. Schiavo, 885 So. 2d 321 (Fla. 2004), *cert. denied*, 543 U.S. 1121 (2005).

[66] MODEL RULES OF PROF'L CONDUCT R. 1.2(b) (2006).

[67] MODEL RULES OF PROF'L CONDUCT R. 2.1.

> necessary protective action, including consulting with individuals or entities that have the ability to take action to protect the client and, in appropriate cases, seeking the appointment of a guardian ad litem, conservator or guardian.[68]

In the *Schiavo* case, the family was at odds over whether to continue treatment *at all*. The litigation that ensued showed just how "aspirational" the client autonomy model embedded in Rule 1.14 can be.[69] Patients who have suffered serious brain injuries that cause significant impairment of their cognitive abilities are, by definition, "not autonomous." Providing effective representation requires the diligent attorney to embark on a crash course of "on the job" training in neurology, cognitive and consciousness disorders, diagnostic imaging, and rehabilitation medicine. An attorney cannot possibly defend the rights of a client with a consciousness disorder or cognitive disability without at least a basic understanding of that disability.

Kendall Coffey's recent article, "Litigating at Light Speed,"[70] is an excellent primer for lawyers who find themselves embroiled in litigation that pushes their legal, organizational, professional, and personal-relations skills (not to mention their physical stamina[71]) to the limit.

> One of the most remarkable battlefields for light speed litigation was the tragic and multi-faceted case of Terri Schiavo. As the entire nation would learn, she was the center of a heartbreaking controversy between her husband and parents concerning the question of whether nutrition and

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[68] MODEL RULES OF PROF'L CONDUCT R. 1.14(b).

[69] For a more in-depth discussion of Rule 1.14, *see infra* Part VI(B).

[70] Kendall Coffey, *Litigating at Light Speed*, 83 FLA. B. J. 20, 25-26 (Jan. 2009).

[71] *Id.* at 26:

> Among other truths about 24/7 lawyering that [George] Felos[, lead counsel for Michael Schiavo,] and [David] Gibbs[, lead counsel for the Schindler family,] emphasize repeatedly are the extraordinary human demands on health and stamina. Gibbs spoke of the "absolutely unbelievable physical, emotional, and mental pressures" confronted in the Schiavo litigation. Correspondingly, in his efforts to meet those challenges, Felos underscored the value of being in good condition before entering a no-sleep zone, where fatigue can be a constant companion even as adversities intensify and magnify.

> hydration should be withdrawn due to the limited brain functions resulting from heart failure 15 years earlier. Following the state trial judge's decision to remove feeding tubes on March 18, 2005, trails were blazed through state and federal courts at trial and appellate levels, lasting until Terri Schiavo's death on March 31, 2005.
>
> The case was litigated by both sides with great ability and a remarkable capacity to respond effectively to some of the most abbreviated and intense deadlines imaginable.[72]

Those of us involved as attorneys in the *Schiavo* case certainly appreciate the compliment. But "the most abbreviated and intense deadlines imaginable"[73] were the least of our worries. The real problem for the attorneys on the Schindlers' team was the lack of a scientifically sound diagnosis based on state-of-the-art diagnostics. Getting one turned out to be an impossible task.

A. First Things First: Brain Injuries Causing Severe Cognitive Disabilities

Brain injuries are common. Traumatic Brain Injury (TBI) "occurs when a sudden trauma causes damage to the brain[, and] can result when the head suddenly and violently hits an object, or when an object pierces the skull and enters brain tissue."[74] Not surprisingly, it is the leading cause of injury and disability in Afghanistan and Iraq.[75] Acquired brain injuries (ABIs) are caused by tumors, blood clots, strokes, seizures, toxic exposures, infections, metabolic disorders, neurotoxic poisoning,

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[72] *Id.* at 25-26.

[73] *Id.* at 26.

[74] National Institute of Neurological Disorders and Stroke, NINDS Traumatic Brain Injury Information Page, *available at* http://www.ninds.nih.gov/disorders/tbi/tbi.htm (last accessed May 3, 2009). *See also* Rehabilitation Institute of Chicago, Brain, *available at* http://www.ric.org/conditions/brain/whatis/index.aspx (last accessed Mar. 9, 2009).

[75] Edgar Jones et al., *Shell Shock and Mild Traumatic Brain Injury: A Historical Review*, 164 AM. J. PSYCHIATRY 1641, 1641 (2007); *see also* Charles W. Hoge et. al., *Mild Traumatic Brain Injury in U.S. Soldiers Returning from Iraq*, 358 NEW ENG. J. MED. 453, 454 (May 15, 2008).

and anoxia (lack of oxygen).[76] Stroke occurs when blood or fluid invades the tissues of the brain.[77] Every year, some 750,000 Americans suffer a stroke,[78] thus making it a leading cause of serious, long-term adult disability in the United States. Terri Schiavo's injury was caused by cortical hypoxia, "a condition in which there is a decrease of oxygen supply to the brain even though there is adequate blood flow."[79] It can be caused by "[d]rowning, strangling, choking, suffocation, cardiac arrest, head trauma, carbon monoxide poisoning, and complications of general anesthesia . . . ."[80]

Whatever the cause, the results of a brain injury can be devastating.

> Approximately half of severely head-injured patients will need surgery to remove or repair hematomas (ruptured blood vessels) or contusions (bruised brain tissue). Disabilities resulting from a TBI depend upon the severity of the injury, the location of the injury, and the age and general health of the individual. Some common disabilities include problems with cognition (thinking, memory, and reasoning), sensory processing (sight, hearing, touch, taste, and smell), communication (expression and understanding), and behavior or mental health (depression, anxiety, personality changes, aggression, acting out, and social inappropriateness). More serious head injuries may result in stupor, an unresponsive state, but one in which an individual can be aroused briefly by a strong stimulus, such as sharp pain; *coma*, a state in which an individual is totally unconscious, unresponsive, unaware, and unarousable; *vegetative state*, in which an individual is

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[76] Rehabilitation Institute of Chicago, Brain, *available at* http://www.ric.org/conditions/brain/whatis/index.aspx (last accessed Mar. 9, 2009).

[77] The National Institutes of Neurological Disorders & Stroke ("NINDS") reports that four million Americans are living with the effects of stroke. *See* NINDS Traumatic Brain Injury Information Page, http://www.ninds.nih.gov/disorders/tbi/tbi.htm (last accessed Mar. 2, 2009).

[78] SHARON BEGLEY, TRAIN YOUR MIND, CHANGE YOUR BRAIN: HOW A NEW SCIENCE REVEALS OUR EXTRAORDINARY POTENTIAL TO TRANSFORM OURSELVES 120 (Ballantine Books 2007).

[79] NINDS Cerebral Hypoxia Information Page, *What is Hypoxia?*, *available at* http://www.ninds.nih.gov/disorders/anoxia/anoxia.htm (last accessed March 4, 2009).

[80] *Id.*

> unconscious and unaware of his or her surroundings, but continues to have a sleep-wake cycle and periods of alertness; and a *persistent vegetative state* (PVS), in which an individual stays in a vegetative state for more than a month.[81]

A lawyer accepting the task of representing any party to a dispute over a brain injury thus has quite a bit of studying to do. In order to offer "effective representation," the lawyer needs to learn as much as possible about the art, science, and politics of neuroscience.[82]

B. The 1990s Conventional Wisdom: A "Hardwired Brain"

The view that the brain is "hardwired" is traceable to the influential, but erroneous, theories of one the founders of modern neurology, Spanish Nobel Laureate Santiago Ramón y Cajal. Writing in 1911, Cajal observed that "[i]n the adult centers [of the brain] the nerve paths are something fixed, ended and immutable."[83]

> Conventional wisdom in neuroscience held that the adult mammalian brain is fixed in two respects: no new neurons are born in it, and the function of the structures that make it up are immutable, so that if genes and development dictate that *this* cluster of neurons will process signals from the eye, and *this* cluster will move the fingers of the right hand, then by god they'll do that and nothing else come hell or high water. There was good reason why all those extravagantly illustrated brain books show the function, size, and location of the brain's structures in permanent ink. As late as 1999, neurologists writing in the prestigious journal *Science* admitted, "We are still taught that the fully mature brain lacks the intrinsic mechanisms needed to replenish neurons and reestablish neuronal networks after acute injury or in response to the

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[81] NINDS Traumatic Brain Injury Page, *What is the Prognosis?*, *available at* http://www.ninds.nih.gov/disorders/tbi/tbi.htm (last accessed Mar. 24, 2009).

[82] MODEL RULES OF PROF'L CONDUCT R. 1.1 (Competence) (2006).

[83] Begley, *supra* note 78 at 5 (quoting SANTIAGO RAMÓN Y CAJAL, HISTOLOGY OF THE NERVOUS SYSTEM OF MAN AND VERTEBRATES (Neely Swanson & Larry Swanson trans., Oxford University Press 1995)).

insidious loss of neurons seen in neurodegenerative diseases."[84]

In the pages that follow, I will make the case that the rejection of neuroplasticity had a profound impact on the litigation, on the autopsy report, and on media accounts of the case.

Today, it is common knowledge that science has yet to unlock even a fraction of the mysteries of the brain and nervous system. In the early 1990s, when Terri Schiavo and Eluana Englaro suffered their respective head injuries, the scientific mainstream was far more confident about what it knew about the adaptive abilities of neurons than it is today. It should not be at all surprising that the lawyers and judges who relied on the conventional scientific wisdom knew even less.

Until quite recently, it was simply assumed that the brain and central nervous system are largely unable to adapt to experience, including injury.[85] Today we know that the opposite is true. The brain and nervous system are enormously adaptive because neurons have the ability to adapt *physically* in response to stimuli and to shift the locus of brain function to compensate for injuries and disease.[86] In the early 1990s, however, advocates for persons with severe cognitive disabilities faced an uphill battle. Those who argued that the nervous system could adapt, rewire itself, and recover at least some of its impaired function if the injured person were enrolled in an aggressive rehabilitation were viewed as charlatans and quacks.[87] This

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[84] *Id.* at 6 (quoting Daniel H. Lowenstein & Jack M. Parent, *Brain, Heal Thyself*, 283 SCIENCE 1126 (Feb. 19, 1999)).

[85] *See infra* text accompanying note 95 ("The doctrine of the unchanging human brain has had profound ramifications, none of them very optimistic. It led neurologists to assume that rehabilitation for adults who had suffered brain damage from a stroke was almost certainly a waste of time.").

[86] See, e.g., Julien Doyon & Habib Benali, *Reorganization and Plasticity in the Adult Brain During Learning of Motor Skills*, 15 CURRENT OPINION IN NEUROBIOLOGY 161-67 (2005); Bogdan Draganski et al., *Changes in Grey Matter Induced by Training: Newly Honed Juggling Skills Show Up as a Transient Feature on a Brain-Imaging Scan*, 427 NATURE 311, 311-12 (Jan. 22, 2004).

[87] *See* National Public Radio, *Science Friday* (Feb. 2, 2007), *available at* http://www.sciencefriday.com/pages/2007/Feb/hour2_020207.html (last accessed, May 1, 2009).

explains much of the skepticism evident in Judge Greer's rulings in the guardianship proceeding. Experts had testified that there was no hope of improvement because she had lost too much of her brain, and that rehabilitation would have been a waste of time.[88]

Even if there had been a book entitled *Neurology and Consciousness Disorders: A Primer for Lawyers and Other Dummies*, reading it during the closing phases of a high-profile case like *Schiavo* would not have been particularly helpful. The

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[88] *See* Transcript of Record at 974, 976, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Oct. 15-17, 20-21, 2002) (providing questioning on cross examination by Pamela Andersen, Esq., to Melvin Greer, M.D., a neurologist, who had been called as a witness by Michael Schiavo. Dr. Greer's direct testimony begins at p. 864, line 24.):

> Q. And you're telling the Court that physical therapy would be of no benefit?
>
> A. That's right. Physical therapy is not a benefit in this circumstance.
>
> Q. Would it have been a benefit in the past?
>
> A. No, the only thing that would have been helpful is if she had a different problem which led, unfortunately, to her being admitted in this terrible state. No, the die was cast when she was found in this anoxic ischemic state and the evolution of the problem was going to be coming. Her doctors did a great job in being able to maintain adequate nutrition and control infection and so forth, but there would be no difference in terms of the outcome.
>
> Q. So you're saying that therapy would have had zero effect on her over the years?
>
> A. That's right.
>
> Q. But this is an inevitable progression?
>
> A. Yes, this is an inevitable progression.
>
> Q. Is she going to inevitably progress into a more contracted state?
>
> A. Well, she's pretty well contracted right now.
>
> Q. When do you think that would have occurred?
>
> A. I'm sorry?
>
> Q. When do you think that would have occurred?
>
> A. Over the course of her first year or two.
>
> Q. So she would have been in The [sic] state of contracture that she is in today by two years out from the injury?
>
> A. No, the contracture continues to become more prominent, but she was in decerebrate positioning. I mean, the contractures were continuing to emerge as a consequence of the joints being maintained and the posturing. And regardless of what one does to try to extend the joint, the contracture will occur because of the [lack of] input from the brain.

record in the *Schiavo* case was developed over the course of a fifteen-year period, during which mainstream neuroscience remained largely in the grip of Santiago Ramón y Cajal's now-discredited theory that the basic structures of the brain are fixed and immutable. It remained so until nearly 2006, when Dr. Edward Taub, of the University of Alabama, Birmingham, and his colleagues "reported the results of the most rigorous trial ever conducted" of "constraint-induced movement therapy."[89] Dr. Taub's rehabilitation experiment entailed immobilizing the patient's *good* arm so that she would be forced to use the "'useless' arm if she wanted to hold something or feed herself or get dressed or do the laborious rehabilitation exercises through which he put patients."[90] Dr. Taub's hypothesis was that "*learning* not to use an affected arm [or other body parts] accounted for much of a stroke patient's disability."[91]

The story of how Dr. Taub and "a few iconoclastic neuroscientists [who successfully] challenged the paradigm that the adult brain cannot change . . ."[92] is told in *Wall Street Journal* science reporter Sharon Begley's book, *Train Your Mind, Change Your Brain*,[93] a slim and eminently readable book that should be required reading for any lawyer retained to handle a case involving a brain injury. It should also be required reading for all those commentators whose opinions about the state of Terri Schiavo's brain were based on facts developed with old technology, shaped by the conventional

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[89] Begley, *supra* note 78, at 121. *See generally,* "Constraint-Induced Movement Therapy," *available at* http://www.strokeassociation.org/presenter.jhtml?identifier=3029931#2006 (last accessed May 3, 2009):

> Constraint-induced movement therapy (CI) forces the use of the affected side by restraining the unaffected side. With CI therapy, the therapist constrains the survivor's unaffected arm in a sling. The survivor then uses his or her affected arm repetitively and intensively for two weeks.

See also, UAB Taub Therapy Clinic, "Constraint Induced Movement Therapy: Why It Works," *available at* http://www.uabhealth.org/13227/.

[90] Begley, *supra* note 78, at 121.

[91] *See id.* at 120. Compare this theory with the testimony of Melvin Greer, M.D., quoted *supra* note 88.

[92] Begley, *supra* note 78, at 8.

[93] *Id.*

wisdom, and defended with a certainty reserved for "true believers" who cannot be bothered by the facts.[94] Begley observes:

> The doctrine of the unchanging human brain has had profound ramifications, none of them very optimistic. It led neurologists to assume that rehabilitation for adults who had suffered brain damage from a stroke was almost certainly a waste of time. It suggested that trying to alter the pathological brain wiring that underlies psychiatric diseases, such as obsessive-compulsive disorder (OCD) and depression, was a fool's errand. And it implied that other brain-based fixities, such as the happiness "set point" to which a person returns after the deepest tragedy or the greatest joy, are as unalterable as Earth's orbit.
>
> But the dogma is wrong. In the last years of the twentieth century, a few iconoclastic neuroscientists challenged the paradigm that the adult brain cannot change and made discovery after discovery that, to the contrary, it retains stunning powers of neuroplasticity. The brain can indeed be rewired. It can expand the area that is wired to move the fingers, forging new connections that underpin the dexterity of an accomplished violinist. It can activate long-dormant wires and run new cables like an electrician bringing a house up to

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[94] *Compare* Kenneth Goodman, *Ethics Schmethics: The Schiavo Case and the Culture Wars*, 61 U. MIAMI L. REV. 863, 865 (2007) ("What you learned from Dr. Cranford, and especially from the slide he showed us, was that Terri Schiavo's cerebral cortex was full of spinal fluid. Moreover, a flat EEG means that the part of your brain that's supposed to do the thinking is not working. It means, as the autopsy showed afterward, that this woman for fifteen years could not see, feel, hear, or experience anything."), *with* Vidya P. Kulkarni, Kaiwen Lin & Selim R. Benbadis, *EEG Findings in the Persistent Vegetative State*, 24 J. CLIN. NEUROPHYSIOLOGY 433-37 (December 2007), *available at* http://www.ncbi.nlm.nih.gov/pubmed/18090523 (last accessed Mar. 25, 2009) (Abstract) ("EEG findings had no association with etiology and varied from one pattern to another in the same patients' EEGs obtained at different times (see table). We conclude that EEG findings in PVS are heterogeneous and too variable to be of diagnostic value."), *and* Adrian M. Owen et al., *Detecting Awareness in the Vegetative State*, 313 SCI. 1402 (Sept. 8, 2006) (noting that recent research "suggests a method by which some noncommunicative patients, including those diagnosed as vegetative, minimally conscious, or locked in, may be able to use their residual cognitive capabilities to communicate their thoughts to those around them by modulating their own neural activity.").

> code, so that regions that once saw can instead feel or hear . . . . [C]ontrary to Ramón y Cajal and most neuroscientists since [Cajal won the Nobel Prize in 1906], the brain can change its physical structure and its wiring long into adulthood.[95]

C. The State of the Art, 2005 Through Early 2009: Detecting Conscious Awareness in Patients Who Are Assumed to Be Vegetative

Consider, if you will, the *possibility* that Terri Schiavo might have been responsive at some cognitive level to friends and family who visited. There was considerable testimony that she was.[96] Consider next the *possibility* that she could have been aware that the PEG tube had been withdrawn, and that she was entering a process of dehydration that would inevitably lead to her death.[97] These are not far-fetched suggestions. The authors of a September 2008 article entitled *Detecting Awareness in the Vegetative State*, have observed that "recent functional neuroimaging studies have suggested that islands of preserved brain function may exist in a small percentage of patients who have been diagnosed as vegetative."[98]

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[95] Begley, *supra* note 78, at 7-8.

[96] *See, e.g., supra* note 88 (providing testimony of Marvin Greer, M.D.); Jay Wolfson, Guardian *Ad Litem* for Theresa Marie Schiavo, A REPORT TO GOVERNOR JEB BUSH AND THE SIXTH JUDICIAL CIRCUIT IN THE MATTER OF THERESA MARIE SCHIAVO (Dec. 1, 2003), *available at* http://abstractappeal.com/schiavo/WolfsonReport.pdf.

[97] *See Last Visit Narrative* from Attorney Barbara Weller, a member of the Schindlers' legal team (Mar. 19, 2005) (on file with author). Ms. Weller's narrative recounts her effort to elicit a reaction from Terri:

> I stood up and leaned over Terri. I took her arms in both of my hands. I said to her, "Terri if you could only say 'I want to live' this whole thing could be over today." I begged her to try very hard to say, "I want to live." To my enormous shock and surprise, Terri's eyes opened wide, she looked me square in the face, and with a look of great concentration, she said, "Ahhhhhhh." Then, seeming to summon up all the strength she had, she virtually screamed, "Waaaaaaaa." She yelled so loudly that Michael Vitadamo, Suzanne's husband, and the female police officer who were then standing together outside Terri's door, clearly heard her. At that point, Terri had a look of anguish on her face that I had never seen before and she seemed to be struggling hard, but was unable to complete the sentence. She became very frustrated and began to cry.

Id.

[98] Owen et al., *supra* note 2, at 1402.

I ask the reader to consider these possibilities, not because I am convinced that Terri Schiavo had any "islands of preserved brain function." No one can know for certain whether she did or did not. Technology existed to measure brain function. It could have been used, but it was not. Nor do I suggest that the experts who stood ready to assist the Schindlers' legal team in the planned *habeas corpus* proceeding would have agreed that the technology available in early 2005 would have "provide[d] a means for detecting conscious awareness in patients who are assumed to be vegetative yet retain cognitive abilities that have evaded detection using [the] standard clinical methods"[99] that were employed by the neurologists in the *Schiavo* case. We will never know the answer to that question either. The autopsy report specifically rejects any assertion that it is possible to make a post-mortem diagnosis concerning Terri Schiavo's post-injury brain function.[100] Those who nevertheless point to the post-mortem size and weight of her brain, including the Chief Medical Examiner, conveniently ignore the fact that the cause of death was dehydration—a process that causes shrinkage in all body tissues.[101] My proposal goes to the ethics of effective representation in cases involving persons with brain injuries and consciousness disorders.

Rule 1.14(b) of the ABA Model Rules of Professional Conduct requires the lawyers for such patients—or those who are seeking to protect their interests—to "take reasonably necessary protective action, including consulting with individuals or entities that have the ability to take action to protect the client."[102] This would include, among other things, a demand that the patient be represented by her own counsel, and

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[99] *Id.* (reporting on the case of a twenty-three-year-old woman who sustained a severe traumatic brain injury in an automobile accident, and their successful attempt to test their hypothesis that she could respond "through her brain activity, rather than through speech or movement.").

[100] *See supra* note 17 (discussing autopsy report); *see also infra* note 141 (discussing autopsy report).

[101] *See* Mayo Clinic.com, *Dehydration*, *available at* http://www.mayoclinic.com/print/dehydration/DS00561/DSECTION=all&METHOD=print (last accessed March 9, 2009).

[102] MODEL RULES OF PROF'L CONDUCT R. 1.14(b) (2006).

that testimony be adduced that develops facts about the patient's condition that rest on the state-of-the-art diagnostic tools available *at the time of the trial.*

The Schindlers' trial team attempted to convince the guardianship court, Florida's Governor and Legislature, the Florida Supreme Court, the Supreme Court of the United States, the President and Congress, the United States District Court for the Middle District of Florida, and the Eleventh Circuit Court of Appeals that Terri Schiavo was entitled to a fair trial. At a minimum, such a trial would have explored:

(1) Terri's physical and cognitive condition and responses;
(2) The efficacy of state-of-the-art rehabilitation techniques for patients assumed to be in a persistent vegetative state;
(3) The physical, psychological, and emotional responses of patients who are dying from lack of nutrition or hydration; and
(4) Testimony from leading experts in the field of consciousness disorders.

But it was not to be. On March 9, 2005, the guardianship court denied a "Motion for Relief from Judgment Pending Contemporary Medical-Psychiatric-Rehabilitative Evaluation of Theresa Marie Schiavo."[103] Judge Greer's opinion expressed confidence in "guardian ad litem Wolfson's report in which he found the evidence of PVS to be compelling."[104] It was a revealing observation, for it captures perfectly the profound practical wisdom of Sharon Begley's observation that "[s]cience doesn't work the way newspapers might have you believe."[105]

Though he has an impressive résumé,[106] I will never

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[103] *See* Order of March 9, 2005, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. 2005) (denying Motion for Relief from Judgment Pending Contemporary Medical-Psychiatric-Rehabilitative Evaluation of Theresa Marie Schiavo).

[104] *Id.* at 5.

[105] Begley, *supra* note 78, at 122.

[106] *See* University of South Florida, *Jay Wolfson, Dr.P.H., J.D.* http://health.usf.edu/publichealth/eoh/jwolfson/index.htm (last accessed Mar. 12, 2009).

understand why the circuit court appointed Dr. Jay Wolfson as Terri Schiavo's guardian *ad litem* during the stay ordered by Governor Bush. Dr. Wolfson is neither a medical doctor, nor a neuroscientist, nor an expert in consciousness disorders. Even if it had been possible for him to review the entire, fifteen-year medical record in the short time he had to evaluate the case, there is nothing in his report or *curriculum vitae* from which one could infer *any* expertise, education, or training that would qualify him as an expert qualified to give a professional opinion regarding the state of Terri Schiavo's consciousness.[107] A close reading of his report discloses exactly what one might expect from an expert who has a doctorate in public health and a law degree:[108] a restatement of the conclusions of the medical experts who testified before Judge Greer. What we needed was an unbiased, and searching, consultative process that involved experts on the cutting edge of research on disorders of consciousness.

Unfortunately, it is not "news" to report that the law is slow to accept advances in science that could cast doubt on the *res judicata* effect of a judgment. In the early years of DNA testing, the Florida courts routinely rejected requests for DNA tests by defense counsel in death penalty cases because of doubts involving their reliability.[109] In *Schiavo*, the accepted wisdom

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[107] *See, e.g.*, Wolfson, *supra* note 23, at 30, where Dr. Wolfson reports that:

> In the month during which the GAL conducted research, interviews and compiled information, he sought to visit with Theresa as often as possible, sometimes daily, and sometimes, more than once each day. During that time, the GAL was not able to independently determine that there were consistent, repetitive, intentional, reproducible interactive and aware activities. When Theresa's mother and father were asked to join the GAL, there was no success in eliciting specific responses. Hours of observed video tape recordings of Theresa offer little objective insight about her awareness and interactive behaviors. There are instances where she appears to respond specifically to her mother. But these are not repetitive or consistent. There were instances during the GAL's visits, when responses seemed possible, but they were not consistent in any way.
>
> This having been said, Theresa has a distinct presence about her . . . . This is the confusing thing for the lay person about persistent vegetative states.

[108] *Id.*

[109] *See* Benedict P. Kuehne, *Criminal Law and Procedure: 1993 Survey of Florida Law*, 18 NOVA L. REV. 235, 259 (1993). Noting the discrepancy between the "general acceptance" test for the admission of scientific evidence applied in Robinson v. Florida,

from the beginning of the trial *through the coroner's final report* was that Terri's *physical* condition was a good proxy for her cognitive abilities. Her physical condition was known at the time of the trial and subsequent hearings, and all of the experts assumed that nothing could have been done to change it.

One of the great tragedies of the *Schiavo* case is that the art and science of neurology were being revolutionized by advances in diagnostic imaging during the final years of the *Schiavo* case. Advanced techniques in rehabilitation medicine were finally focusing on rebuilding the neural pathways that had atrophied from nonuse. The "advocacy gap" created by the lack of a guardian *ad litem* represented by counsel for Terri alone thus created a "knowledge gap" that allowed the court to rely on a parade of well-known experts who were, themselves, mired in the "conventional wisdom," and a "high quality CT scan" of the physical structure of Terri Schiavo's brain that told the court absolutely nothing about the possibility that there might be "islands of cognition" discoverable by more advanced imaging techniques.[110] As Begley observes:

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610 So. 2d 1288 (Fla. 1992) (admissibility of DNA testing in capital case), and the approach taken by the Supreme Court of the United States under Rule 702 of the Federal Rules of Evidence, the author provided the following:

> Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Id. (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592-93 (1993)).

[110] Functional magnetic resonance imaging (fMRI) is only one such technique. *See* Nicholas D. Schiff, *Multimodal Neuroimaging Approaches to Disorders Of Consciousness*, 21 J. HEAD TRAUMA REHAB. 388, abstract (Sept.-Oct. 2006), *available at* http://www.ncbi.nlm.nih.gov/pubmed/16983224 (last accessed Mar. 10, 2009):

> Multimodal neuroimaging studies using positron emission tomography techniques, functional magnetic resonance imaging, and quantitative electroencephalography and magnetoencephalography quantify variations of residual cerebral activity across these patient populations. The results suggest models to distinguish the pathophysiologic basis of VS and MCS. Less clear are potential brain mechanisms underlying late recovery of communication in rare MCS patients. Diffusion tensor magnetic resonance imaging studies and recent experimental findings suggest that structural remodeling of the brain following severe injury may play a role in late functional recoveries . . . .

> If you are attacking the dogma [of neuroscience], you don't make a lot of friends . . . . [The rejection of neuroplasticity is] yet another dogma that is now in the dustbin of history . . . . This was yet another case where science has deemed something impossible without really ruling it out empirically.[111]

The "conventional wisdom" regarding brain structure, cognitive function, and neural plasticity died hard.[112] As late as 2006, "[t]he rehab community was united in opposition to the idea that therapy after a stroke could reverse the neurological effects of the infarct," and "'[t]he official position of the American Stroke Association was that rehab for patients with chronic stroke only increases a patient's muscular strength and confidence,' but does nothing to address the brain damage."[113] When advocacy organizations of the stature of the American Stroke Association were willing to assert—in the face of convincing evidence to the contrary—that rehabilitation of stroke victims was a fool's errand, we can begin to understand the reasons why "[t]he vegetative state is one of the least understood and most ethically troublesome conditions in modern medicine."[114]

> Because neuroplasticity and the power of mind and mental training effect changes in the very structure and function of our brain, free will and moral responsibility become meaningful in a way that they have not been for some time in the scientific West . . . . The conscious act of thinking about one's thoughts in a different way changes the very brain circuits that do that thinking . . . . As the discoveries of neuroplasticity, and this self-directed neuroplasticity, trickle

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[111] Interview by Ira Flatow with Sharon Begley, science reporter for *The Wall Street Journal* and author of TRAIN YOUR MIND, CHANGE YOUR BRAIN, in National Public Radio, *Science Friday* (Feb. 2, 2007), *available at* http://www.sciencefriday.com/pages/2007/Feb/hour2_020207.html (follow link for mp3 file of brain interview) (last accessed Feb. 3, 2007).

[112] *See* Letter from Stephen J. Nelson, Chief Medical Examiner, 10th Judicial Circuit of Florida, to Jon R. Thogmartin, District 6 Medical Examiner 9 (June 8, 2005) (Neuropathology Report) in THOGMARTIN, *supra* note 4, at 20.

[113] Begley, *supra* note 78, at 121.

[114] Owen et al., *supra* note 2.

> down to clinics and schools and plain old living rooms, the ability to willfully change the brain will become a central part of our lives—and of our understanding of what it means to be human.[115]

III. TOWARDS A MODEL OF ETHICAL PROFESSIONALISM

Doctors, nurses, allied health-care professionals, and researchers from every profession have weighty professional responsibilities. These duties do not exist in the abstract. They arise from and govern the relationships formed with those who need, and rely upon their knowledge, expertise, good judgment, and artistry.[116]

It is impossible to understand the claims made on Terri Schiavo's behalf by her parents in the final stages of the case, or the lengths to which the political branches of the State of Florida and the United States government went in their attempts to vindicate this young woman's right to a fair trial, without also understanding that none of these efforts would have been necessary had the courts and the media been open to the possibility that the conventional wisdom was—as it almost always is—wrong. James L. Bernat put it this way:

> The findings of Eric Racine and colleagues in this issue of *Neurology* are important to understand how the media accounts of her case shaped public opinion. They found that articles published by print media outlets frequently contained scientific inaccuracies, inconsistent diagnostic and descriptive terminology, mismatches between the descriptions of her state and the medical terms used to characterize it, inaccurate prognoses, an inability to distinguish expert opinion from diatribe, and emotionally or politically charged language misleadingly describing end-of-life care. Sadly, media attempts to define and explain disorders of consciousness were

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[115] Begley, *supra* note 68, at 253-54.

[116] *See, e.g.*, Michael D. Bayless, PROFESSIONAL ETHICS (2nd ed., Wadsworth 1989); CONFLICT OF INTEREST IN THE PROFESSIONS (Michael Davis & Andrew Stark eds., Oxford University Press 2001); THE CRISIS OF CARE: *Affirming and Restoring Caring Practices in the Helping Professions* (Susan S. Phillips & Patricia Benner eds., Georgetown University Press 1994).

infrequent.

> . . . But the most serious media shortcoming was squandering the opportunity to educate the public about disorders of consciousness and end-of-life care. The power of the media to mold public opinion imparts a duty for them to conduct public education.[117]

The same holds true for lawyers and judges. At the center of all of our respective professional endeavors is a human person—a patient, a client, a research subject, or a party who has an interest in the outcome of our efforts. We must be free, we argue, to perform our respective duties as professionals because both "skill" and "judgment" are a uniquely personal combination of art and science:

> Every science touches art at some points—every art has its scientific side; the worst man of science is he who is never an artist, and the worst artist is he who is never a man of science. In early times, medicine was an art, which took its place at the side of poetry and painting; today they try to make a science of it, placing it beside mathematics, astronomy, and physics.[118]

A similar combination of art and science explains the profoundly important role that lawyers and judges play in the

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[117] James L. Bernat, Editorial, *Theresa Schiavo's Tragedy, and Ours Too*, 71 NEUROLOGY 964, 964-65 (Sept. 23, 2008); *see also* Timothy Johnson, *Shattuck Lecture; Medicine and the Media*, 339 NEW ENGLAND J MED. 87 (July 9, 1998). The article referenced by the Bernat editorial, Eric Racine et al., 71 NEUROLOGY 1027, 1030 (2008) expands on the point made in the text:

> Given the centrality of the PVS diagnosis in the Schiavo case, our results highlight areas critical for the public understanding of the CDCs (chronic disorders of consciousness). The results confirm concerns expressed in the peer-review literature that media coverage of the case of Terri Schiavo included both inaccurate statements about her diagnosis and charged language about EOL (end-of-life) decision-making (references: Perry, J.E., Churchill, L.R., Kirshner, H.S., The Terri Schiavo case: legal, ethical, and medical perspectives. Ann Intern Med 2005; 143: 744-748 and Quill, T.E., Terri Schiavo: a tragedy compounded. N Engl J Med 2005; 352:1630-1633).

Id. (referencing James L. Bernat, *Chronic Disorders of Consciousness*, 367 THE LANCET 1181 (2006)).

[118] A.L. Wynman, *Endpiece—Medicine: Art or Science*, 320 British Med. J. 1322 (2000) (quoting ARMAND TROUSSEAU, LECTURES ON CLINICAL MEDICINE (Vol. 2, The New Syndeham Society 1869)).

regulation of health care. By law and the ethics of their profession, lawyers are the gatekeepers and administrators of the justice system. We serve as the civil and criminal investigators, evaluators, and ""judges"" of first instance. It is our responsibility to ensure that no case under our control proceeds to a judge, or to a grand or petit jury, unless the evidence supporting the alleged grievance, crime, or defense is both admissible in court and strong enough to withstand the rigors of cross-examination.[119] As the "arbiter of facts and law for the resolution of disputes and a highly visible symbol of government under the rule of law,"[120] the judge is legally and ethically obligated to "administer justice without respect to persons, and do equal right to the poor and to the rich . . . ."[121]

Read together, the ethics of both law and medicine thus lead inexorably to the conclusion that the boundary between law and medicine is defined by the consistent application of a rule of reason to the facts and circumstances of each case.[122] Because duty is our common calling, a "professional responsibility" (or "duty") model provides a powerful and precision-crafted lens through which to examine *any* decision, act, or omission by a legal or medical professional.

Viewed through this lens rather than the "real-time" glare of the twenty-four hour news cycle, the *Schiavo* case is a textbook example of questionable behavior *across the board.*

IV. THE ETHICS OF DUE PROCESS AND EQUAL PROTECTION IN

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[119] *See* MODEL RULES OF PROF'L CONDUCT R. 3.1 (2006).

[120] MODEL CODE OF JUDICIAL CONDUCT Preamble (2007).

[121] 28 U.S.C. § 453 (2007). The material quoted in the text is drawn from chapter 28, section 453 of the United States Code, which prescribes the Oath of Office for each judge or justice of the United States. *See also* MODEL CODE OF JUDICIAL CONDUCT Canon 3 (2006).

[122] Bolitho v. City and Hackney Health Auth., [1998] A.C. 232 (H.L.) (holding that "there are cases where, despite a body of professional opinion sanctioning the defendants' conduct, the defendant can properly be held liable for negligence . . . [when] it cannot be demonstrated to the judge's satisfaction that the body of opinion relied upon is reasonable or responsible."). Justice Farquharson made much the same point in the jury instructions delivered in *R. v. Arthur*, [1981] 12 B.M.L.R. 1 ("There is no special law in this country that places doctors in a separate category and gives them extra protection over the rest of us.").

DISPUTED PROCEEDINGS TO WITHDRAW NUTRITION AND HYDRATION FROM BRAIN-INJURED PATIENTS

A. The Role of the Courts in a Disputed Guardianship Case

Properly understood, the law provides a framework within which those who are empowered to decide difficult medical questions can do so without fear of criminal or civil liability. In the Anglo-American common law tradition that prevails in the United Kingdom, the Commonwealth countries, and the United States, the courts provide a forum for the formal *and final* resolution of public and private disputes, including those involving medical care.

In an ideal world, disputes among family members, between physicians and their patients, or among partisans in the field of medical or biological research would be rare. Unfortunately, they are all too common, and when one of the parties to such a dispute invokes the power of the court to resolve it, the "justice" of the outcome will depend not only on the strength of their respective medical and legal positions, but also on the quality of the legal process itself.

This point cannot be over-emphasized. The role of the judge is to preside over an adversarial hearing in which the parties and their counsel, not the court, must shoulder the burden of presenting enough facts to permit either the judge or a jury to resolve the factual issues in dispute. Where cases involve difficult questions relating to diagnosis or treatment, the law will often defer to medical experts, but judicial deference cannot be assumed. The parties must prove, to the satisfaction of the judge, that the law provides a remedy (including deference) under the circumstances.[123] As a result, the duty of a legal guardian, guardian *ad litem*, prosecutor, or counsel for one of the parties is to get as many of the relevant facts on the table as possible. If there is a default by any one of the parties to a case, the quality of justice will suffer.

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[123] *Compare* FLA. STAT. § 764.361 (2007) (discussing powers of guardian); *with* § 765.401 (discussing powers of proxy in the absence of an advance directive); § 765.404 (discussing persons in a persistent vegetative state).

This article proposes that inquiries of this type are best conducted in the language of professional ethics. The professional norms common to criminal and civil cases provide not only a set of readily accessible and commonly accepted definitions of the rights and obligations of those having an interest in the outcome, but they also provide a powerful lens through which we can analyze the often-erroneous factual assumptions that drive the "conventional wisdom."

B. The Relevance of the Law of Homicide

"Homicide" is defined by the common law as "the killing of one person by another."[124] It has two purposes: 1) to protect the living from homicidal acts or omissions; and 2) to protect those who become parties to a post-mortem inquiry into the reasons why a specific death occurred. Florida law does not expressly define the term homicide,[125] but it does impose criminal liability for specific acts or omissions.[126] In most cases, the physician's role is limited to making the initial determination that the patient has died and filing the appropriate death certificate.[127] If the cause of death is extraordinary in any way, such as by violence or under unusual circumstances, the medical examiner or coroner has the authority "to perform, or have performed, whatever autopsies or laboratory examinations he or she deems necessary and in the public interest to determine the identification of or cause or manner of death of the deceased or to obtain evidence necessary for forensic examination[,]" and, thereafter, to make it available to the appropriate legal authorities.[128]

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[124] *See* BLACK'S LAW DICTIONARY 751 (8th ed. 2004).

[125] Florida Statutes section 775.01 provides that "[t]he common law of England in relation to crimes, except so far as the same relates to the modes and degrees of punishment, shall be of full force in this state where there is no existing provision by statute on the subject."

[126] *See, e.g.,* FLA. STAT. § 782.03 (excusable homicide); § 782.04 (murder); § 782.07 (manslaughter); § 782.071 (vehicular homicide); § 782.08 (assisting in self-murder, defined in § 781.081(1)(b) as "the voluntary and intentional taking of one's own life. As used in this section, the term includes attempted self-murder.").

[127] *See, e.g.,* FLA. STAT. § 382.008 (2007).

[128] *See, e.g.,* FLA. STAT § 406.11 (2007).

There are only two situations in American law in which the execution of a judicial decree authorizes acts taken with the *express* intention of *causing* death. The first is the death penalty;[129] the other is a judicial decree authorizing families, physicians, or medical facilities to withhold or terminate life-sustaining care from an incompetent person.[130]

Laws authorizing the execution of a death sentence make it clear that capital punishment is an exception to the general rule prohibiting acts or omissions "perpetrated from a premeditated design to effect the death of the person killed or any human being . . . ."[131] Because death is a sentencing option in these cases, the law requires effective representation of counsel[132] and other procedural safeguards that are supposed to ensure that the trial, appeals, and sentencing are conducted fairly.[133] If the sentence is actually carried out, the law also requires that the method of execution be neither cruel nor unusual.[134]

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[129] *See, e.g.*, FLA. STAT. § 922.105(1) (2007) ("A death sentence shall be executed by lethal injection, unless the person sentenced to death affirmatively elects to be executed by electrocution. The sentence shall be executed under the direction of the Secretary of Corrections or the secretary's designee.").

[130] Laws expressly authorizing euthanasia at the request of a competent patient are distinguishable from the execution of a judicial decree ordering an act or omission intended to cause death. Assisted suicide statutes immunize, under certain conditions, actions that might otherwise make them accessories to homicide. *See* O.R.S. §161.155 (2009). Section 127.805 of Oregon's assisted suicide statute, O.R.S. §§127.000-127.897 (2009), authorizes an adult who is certified by a physician to be terminally ill "to make a written request for medication for the purpose of ending his or her life in a humane and dignified manner." Fully informed consent, verified in writing by the physician, is required. O.R.S. §§ 127.820, 127.825, 125.830 (2009).

[131] FLA. STAT. § 782.04 (2007) (defining "murder"). *Compare* § 922.105(5)-(8) (creating an exception to the general rule defining "murder" to exclude the acts or omissions necessary to execute a death sentence).

[132] Keith Cunningham-Parmeter, *Dreaming of Effective Assistance: The Awakening of Cronic's Call to Presume Prejudice from Representational Absence*, 76 TEMP. L. REV. 827 (2003).

[133] *See generally* Rob Warden, *Illinois Death Penalty Reform: How It Happened, What It Promises*, 95 J. CRIM. L. & CRIMINOLOGY 381 (2005).

[134] *Compare* FLA. STAT. § 922.105(8) (2007) ("In any case in which an execution method is declared unconstitutional, the death sentence shall remain in force until the sentence can be lawfully executed by any valid method of execution."); *with* § 782.03 ("Homicide is excusable when committed by accident and misfortune in doing any lawful act by lawful means with usual ordinary caution, and without any unlawful intent, . . . and not done in a cruel or unusual manner."). *See generally* Philip R. Nugent, *Pulling*

A judicial decree authorizing acts or omissions that will inevitably result in the death of an incompetent person presents equally difficult legal and judicial ethics issues.[135] Death is not only the inevitable consequence of such decrees; it is, in many cases, the *intended* result. Even though the law and many commentators draw a distinction in such cases between acts or omissions, or between direct and indirect effects, the fact remains that:

> [I]n many termination of treatment cases, it is specious to say that death is unintended. That explanation makes sense in administration of pain medication that is foreseeably lethal. It is also true where the decision to terminate life support is genuinely directed to the treatment, independent of its role in keeping the patient alive . . . . But this reasoning does not apply to many decisions to cease a life-sustaining procedure. Often what the patients or the families want to end are lives so impoverished and hopeless that they are judged not worth living. Despite repeated rejection of suicide and euthanasia, judicial decisions approving the right to such terminations make clear the judges' own sympathies with this judgment. The miserable existence suffered by the patient (apart from the procedure to be ended) is often described in heart-breaking detail.[136]

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the Plug on the Electric Chair: The Unconstitutionality of Electrocution, 2 WM. & MARY BILL RTS. J. 185 (1993).

[135] MODEL RULES OF PROF'L CONDUCT (2006); MODEL CODE OF JUDICIAL CONDUCT (2007).

[136] Richard S. Kay, *Causing Death for Compassionate Reasons in American Law*, 54 AM. J. COMP. L. (SUPP.) 693, 714 (2006) (internal citations omitted). The Florida courts provided just such detail in *Schiavo*:

> The evidence is overwhelming that Theresa is in a permanent or persistent vegetative state. It is important to understand that a persistent vegetative state is not simply a coma. She is not asleep. She has cycles of apparent wakefulness and apparent sleep without any cognition or awareness. As she breathes, she often makes moaning sounds. Theresa has severe contractures of her hands, elbows, knees, and feet. Over the span of this last decade, Theresa's brain has deteriorated because of the lack of oxygen it suffered at the time of the heart attack. By mid 1996, the CAT scans of her brain showed a severely abnormal structure. At this point, much of her cerebral cortex is simply gone and has been replaced by cerebral spinal fluid. Medicine cannot cure this condition. Unless an act of God, a true miracle, were to recreate her brain, Theresa will always remain in an unconscious, reflexive state, totally

It is clear from an examination of the record and published opinions in the *Schiavo* case that the stated justification for the orders entered by the Probate Court was that Terri had told her husband's relatives that she would not want to be maintained in a severely incapacitated condition.[137] It is also clear that this alleged desire was the one that the Probate Court of Pinellas County Florida sought to effectuate in Terri Schiavo's case.[138] Consider the sequence of the orders entered by the court:[139]

- *The decree of February 11, 2000,* authorized the guardian, Michael Schiavo, to "proceed with the discontinuance of said *artificial life support* for Theresa Marie Schiavo."[140] Such a decree is not, by its terms, an order authorizing acts or omissions that will inevitably result in the death of the incompetent ward. Although death may well result from the discontinuance of artificial life support, it is

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dependent upon others to feed her and care for her most private needs. She could remain in this state for many years.

In re Guardianship of Schiavo, 780 So. 2d 176, 177 (Fla. Dist. Ct. App. 2001) (*Schiavo I*) (internal citations omitted).

[137] *See* Transcript of Trial at 372, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Apr. 17, 2000) (testimony of Mary Schindler on January 25, 2000); Excerpts of Trial at 53-90, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Feb. 11, 2000) (testimony of Diane Myer on January 26, 2000, and testimony of Michael Schiavo, Scott Schiavo, and Joan Schiavo). The trial court also heard the testimony from a priest who had never met Terri, apparently in order to establish that the views attributed to Terri were consistent with Terri's personal faith and the stated position of the Catholic Church on withholding nutrition and hydration. Transcript of Trial at 178-223, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. 2000), *available at* http://www6.miami.edu/ethics/schiavo/doc_files/Testimony_of_Father_Gerard_Murphy.doc, at 28, 36-37 (testimony of Father Gerard Murphy: "Have you had the opportunity to meet Mr. and Mrs. Schindler? A: No. I regret that. I wish I were their pastor. Q: Have you had the opportunity to meet Theresa Schiavo in this case? A: No . . . . Q: So in this case, have you had the benefit of any of the other family's . . . A. No . . . . Q: -- thoughts on this? A: No . . . .").

[138] *Schiavo I*, 780 So. 2d at 180 ("Her statements to her friends and family about the dying process were few and they were oral. Nevertheless, those statements, along with other evidence about Theresa, gave the trial court a sufficient basis to make this decision for her.").

[139] All references to court orders are to the guardianship case: *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. 2000).

[140] Order of February 11, 2000, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. 2000) (emphasis added).

always *possible* that a person sustained by artificial nutrition and hydration can survive by ingesting food and water by mouth. Whether, and at what point, oral ingestion would have been possible for Terri Schiavo in late 2003 and in 2005 is a matter of some dispute.[141]

- *The decree dated September 17, 2003*, by contrast, directed that the guardian, Michael Schiavo, "shall cause the *removal of the* nutrition and hydration *tube* from the Ward, Theresa Marie Schiavo."[142] That particular tube was removed pursuant to the court's order.[143] In accordance with the Executive Order authorized by "Terri's Law," another tube was inserted later. The Governor's action precipitated the litigation in *Schiavo v. Bush*.
- *The final decree issued by Judge Greer on February 25, 2005,* directed "that the guardian, Michael Schiavo, shall cause the removal *of nutrition and hydration* from the

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[141] The autopsy takes the position that oral nutrition and hydration would have been impossible given the condition of Terri's throat musculature at the time of her death from dehydration. THOGMARTIN, *supra* note 4, at 7, Question #3. The family, by contrast, argues that, with proper rehabilitation and training, Terri could have been taught to swallow, and there were indications in the medical records that she had, in the early 1990s, both taken liquids and responded on one occasion to a question.

In this regard, the Medical Examiner and the family are talking past each other. The Medical Examiner's Report describes only the condition of the body after death and draws a careful distinction between a medical diagnosis and a *post-mortem* examination. The family's position, by contrast, focuses on their longstanding argument that the failure to provide rehabilitation services after the diagnosis of PVS was medical neglect. This argument may well be supported by advances in rehabilitation medicine and the scientific community's increasing awareness that the neuroplasticity of the brain makes it possible to regain physical and mental functions that were once thought to be irreversibly lost due to trauma or disease. *See, e.g.*, SHARON BEGLEY, TRAIN YOUR MIND, CHANGE YOUR BRAIN: HOW A NEW SCIENCE REVEALS OUR EXTRAORDINARY POTENTIAL TO TRANSFORM OURSELVES (Ballantine Books, 2006); *and* JEFFREY M. SCHWARTZ & SHARON BEGLEY, THE MIND AND THE BRAIN: NEUROPLASTICITY AND THE POWER OF MENTAL FORCE (Harper Collins 2002).

[142] Order of September 17, 2003, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Sept. 17, 2003) (emphasis added).

[143] *See* Fla. Exec. Order No. 03-201 (Oct. 21, 2003) (noting that "the action of withholding or withdrawing nutrition or hydration from a patient in a permanent vegetative state has already occurred."), *available at* http://news.findlaw.com/hdocs/docs/schiavo/flagovexord03201.html.

ward, Theresa Schiavo."[144] This order was unquestionably designed to ensure that Terri Schiavo's life would end—a point underscored by Judge Greer's ruling on the "Emergency Expedited Motion to Provide Theresa Schiavo with Food and Water by Natural Means" filed on February 28, 2005, by Terri's parents, Robert and Mary Schindler.[145] In that motion, Terri's parents asked that they be permitted to provide food and water to their daughter by mouth.[146] Judge Greer denied the motion on March 8, 2005, because, in his view, their request was the medical equivalent of "asking for an experimental procedure."[147] A police guard was then posted outside Terri's room in order to ensure that no fluids were provided.[148]

Because section 782.03 of the Florida Statutes excuses only acts taken "by lawful means with usual ordinary caution, and without any unlawful intent, . . . and not done in a cruel or unusual manner[,]" the timing and manner of death is relevant. In Terri Schiavo's case, "[p]ostmortem findings, including the state of the body and laboratory testing, show that she died of marked dehydration (a direct complication of the electrolyte disturbances brought about by the lack of hydration)."[149] Were the patient capable of experiencing the pain and mental anguish that would attend such a horrible demise, there would be no

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[144] Order of February 25, 2005, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Feb. 25, 2005) (emphasis added). *But see infra* text accompanying note 149.

[145] Order of March 8, 2005, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Mar. 8, 2005).

[146] Emergency Expedited Motion to Provide Theresa Schiavo with Food and Water by Natural Means, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Feb. 28, 2005).

[147] Order of March 8, 2005, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. March 8, 2005).

[148] *See* Anne Lindenberg, *In Schiavo Case, Police Rely on Professionalism*, ST. PETERSBURG TIMES, Apr. 11, 2005, at Largo Times 3.

[149] THOGMARTIN, *supra* note 4, at 39, p. 8, Question 7 ("By what mechanism did Theresa Schiavo die?"). Because the Medical Examiner could not determine the cause of the "severe anoxic brain injury . . . with reasonable medical certainty[, the] manner of death will therefore be certified as undetermined."); *id.* at 39, p. 9, Question 8 ("What was the cause and manner of death?").

doubt that utilizing such a method for ending the person's life would be "cruel and unusual"—if not barbaric. Theresa Schiavo's *actual* cognitive abilities at the time of her death were thus a critically important—but unknown—fact.[150]

C. Comparing the Substantive and Procedural Requirements in Capital Punishment and Disputed Withdrawal of Treatment Cases

In *Florida v. Davis*,[151] the Florida Supreme Court made the following statement concerning the unique nature of cases in which a judicial decree will result in death:

> As the United States Supreme Court first stated more than twenty-five years ago, "death is different in kind from any other punishment imposed under our system of criminal justice."[152] We have acknowledged that "death is different" in recognizing the need for effective counsel in capital proceedings "from the perspective of both the sovereign state and the defending citizen."[153]

Terri Schiavo was not dead when these orders were entered. She was incapacitated and uniquely vulnerable, but also entitled as a matter of Florida constitutional law to have a surrogate exercise her right to decide whether to continue further nutrition and hydration.[154] Florida lawmakers responded to the problems created by the concept of "substituted judgment" by creating a conditional immunity for those involved in the inquiry. As long as health care facilities, providers, surrogates, and proxies follow the procedures prescribed in Chapter 765 of the Florida Statutes, and there is a finding, based on clear and convincing evidence, that the incapacitated person had given some indication that he or she would have refused life-sustaining treatment under the circumstances, the

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[150] *Id.* at 39, p. 8, Questions 5 ("Was Mrs. Schiavo in a persistent vegetative state?") and 6 ("What diagnoses can be made in regards to the brain of Mrs. Schiavo?").

[151] Florida v. Davis, 872 So. 2d 250, 254 (Fla. 2004).

[152] *Id.* (quoting Gregg v. Georgia, 428 U.S. 153, 188 (1976)). Also in support of this proposition, the court cited Florida v. Dixon, 283 So. 2d 1, 7 (Fla. 1973) (stating that because "[d]eath is a unique punishment in its finality and in its total rejection of the possibility of rehabilitation . . . , the Legislature has chosen to reserve its application to only the most aggravated and unmitigated of most serious crimes.").

[153] Davis, 872 So. 2d at 255 (quoting Sheppard & White, P.A. v. Jacksonville, 827 So. 2d 925, 932 (Fla. 2002)).

[154] *In re* Guardianship of Browning, 568 So. 2d 4 (Fla.1990).

surrogate may act.[155] That immunity, however, is expressly conditioned on two factors. The first is compliance with specific due process requirements. The second is the development of factual findings concerning the incapacitated person's physical, mental, or and cognitive condition.

Careful examination of the procedural requirements in capital cases and disputed withdrawal of treatment cases leaves little doubt that Florida law treats all cases in which judges are asked to authorize actions or omissions that would otherwise be subject to prosecution under the laws governing homicide as "death cases."[156] There are, however, important differences.

In a capital punishment case, the defendant is usually competent to stand trial and can participate in the defense of his or her case. There is an extensive body of constitutional and statutory law that mandates "effective assistance of counsel," and a vocal—and growing—group of individuals and organizations who are willing and able to delay execution of a death sentence for years in order to ensure that the trial was conducted fairly and that the court's findings of fact are *objectively* verifiable (*i.e.*, that the defendant is actually guilty).[157]

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[155] FLA. STAT. § 765.109 (2007) (discussing immunity from liability).

[156] Section 765.401(3) of the Florida Statutes requires that substituted judgment proceedings comply with section 765.205, which defines the powers of the surrogate decision-maker, and section 765.305, which deals with procedure where there is no advance directive. Both statutes contemplate compliance with Chapter 744 (governing guardians and their powers), as well as the possibility that life-sustaining treatment can be withdrawn, even in the absence of evidence concerning the patient's wishes, in cases where the patient is in a persistent vegetative state. *See* FLA. STAT. § 765.404 (2007).

[157] The Innocence Project is an excellent and inspirational example of an organization that seeks to ensure that individuals are not wrongly convicted. It was founded in 1992, by Barry C. Scheck and Peter J. Neufeld at the Benjamin N. Cardozo School of Law at Yeshiva University, to assist prisoners who could be proven innocent through DNA testing. This path-breaking, nonprofit legal clinic's efforts have now been duplicated at law schools throughout the country. Its website accurately observes that the facts and procedural issues of each case are unique, but that examination of the cases in which mistakes have been found show that there are a number of common issues: "[1] Unreliable or Limited Science[; 2] False Confessions[; 3] Forensic Science Fraud or Misconduct[; 4] Government Misconduct[; 5] Informants or Snitches[; and 6] Bad Lawyering." *See* The Innocence Project, *The Causes of Wrongful Conviction*, http://www.innocenceproject.org/understand (last accessed, Mar. 5, 2009).

The *Schiavo* case proves that precisely the opposite can be true in a disputed "substituted judgment" case. The client is under a severe "disability" as that term is understood in both civil rights law and legal ethics. The disability that gives rise to the claim that treatment should not continue makes it impossible for the incapacitated person to participate in a trial or to indicate his or her present preferences in any way. Although Florida prescribed almost exactly the same procedural safeguards for such cases as it does in capital punishment cases,[158] the courts were willing either to dispense with them, or to view them as impediments standing in the way of effectuating the court's decision that the incapacitated wards would have chosen to refuse life-sustaining care under the circumstances.[159]

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[158] In section 744.1012 of the Florida Statutes, the Florida Legislature expressed its intent as follows:

> Recognizing that every individual has unique needs and differing abilities, the Legislature declares that it is the purpose of [the Guardianship Statute] to promote the public welfare by establishing a system that permits incapacitated persons to participate as fully as possible in all decisions affecting them; that assists such persons in meeting the essential requirements for their physical health and safety, in protecting their rights, in managing their financial resources, and in developing or regaining their abilities to the maximum extent possible; and that accomplishes these objectives through providing, in each case, the form of assistance that least interferes with the legal capacity of a person to act in her or his own behalf.

Florida Statutes section 765.102(1) states the legislative intent of Florida's Advance Directive Statutes:

> (1) The Legislature finds that every competent adult has the fundamental right of self-determination regarding decisions pertaining to his or her own health, including the right to choose or refuse medical treatment. This right is subject to certain interests of society, such as the protection of human life and the preservation of ethical standards in the medical profession.

The Florida Declaration of Rights provides explicit protection for the "Rights of Accused and Victims." FLA. CONST. art. I, § 16. Section 17 provides detailed guidance concerning the legality of the death penalty and the manner in which it is to be executed. FLA. CONST. art. I, § 17 ("Excessive Punishments").

[159] Among other omissions, Terri Schiavo was never represented by counsel whose independent professional judgment was not compromised by either real or apparent conflicts with the interests of her husband and guardian, Michael Schiavo, or those of the Schindler family, who sought to have Mr. Schiavo removed as guardian. *See, e.g., In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Sept. 3, 1999) (order authorizing payment of interim cost advance to attorney); *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Mar. 11, 1998) (order authorizing payment of cost retainer to attorney instituting action regarding withdrawal of life support systems); *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. May 14, 1997) (order

When Terri's parents and pro-life activists stepped forward to question the procedural fairness of the trial, they were described not as zealous guardians of the right to a fair trial and the rights of the accused, but as "those who wanted to keep [Terri] alive indefinitely—including her elderly parents" and "politicized religious forces [who] were responsible for the international attention garnered by Mrs. Schiavo's plight and the escalation of her cause to a culture war flashpoint."[160] And when Terri's family asked that state-of-the-art diagnostics, such as functional magnetic resonance imaging (fMRI), be used to test her actual, as opposed to assumed, cognitive state, the court refused the request.[161]

V. DISTINGUISHING BETWEEN THE FACTS OF A CASE AND THE "RECORD OF ITS PROCEEDINGS"

I joined the Terri Schiavo case as appellate co-counsel in the Florida Supreme Court[162] for Florida Governor Jeb Bush in early August, 2004. Later that month, after having immersed myself in the trial record and all of the briefs filed to that point, I argued the case for the constitutionality of "Terri's Law"[163] and the Governor's October 2003 Executive Order restoring the nutrition and hydration tube sustaining Terri Schiavo's life[164]

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authorizing guardian to employ and pay an attorney).

[160] Joshua E. Perry, *Biblical Bio-Politics: Judicial Process, Religious Rhetoric, Terri Schiavo and Beyond*, 16 HEALTH MATRIX 553 (2006).

[161] *See* Order Denying FLA. R. CIV. P. 1.540(b)(5) Motion for Relief from Judgment Pending Contemporary Medical-Psychiatric-Rehabilitative Evaluation of Theresa Marie Schiavo of March 9, 2005, *In re* Guardianship of Schiavo, No. 90-2908-GD-003 (Fla. Cir. Ct. Mar. 9, 2005) (order authorizing guardian to employ and pay an attorney). As used in the text, the term "state of the art diagnostics" should not be equated with functional magnetic resonance imaging (fMRI). In November, 1990, approximately nine months after she collapsed, surgeons implanted a nine-centimeter-long neurological thalamic stimulator wire in Terri Schiavo's head. It extended from the right parietal bone and terminated in the right thalamus.

[162] The case was argued in the Florida Supreme Court on August 31, 2004. The transcript of the oral argument is available at http://www.wfsu.org/gavel2gavel/transcript/04-925.htm . The video is available at http://www.wfsu.org/gavel2gavel/archives/04-08.html.

[163] 2003 Fla. Laws 418, *available at* http://election.dos.state.fl.us/laws/03laws/ch_2003-418.pdf.

[164] Fla. Exec. Order No. 03-201 (Oct. 21, 2003), *available at*

after Judge Greer's September 17, 2003, order that it be withdrawn.[165] From that review of the record, it became clear to me that the *Schiavo* case had all of the characteristics of a problematic death penalty case: serious procedural errors, ineffective assistance from her guardian, no assistance of counsel, and a judge who had overstepped the proper boundaries of his judicial role. Whatever the actual facts were in the *Schiavo* case, neither I nor an appellate court, whose review would be limited to the trial court's record, could ever know them from that source. It is my contention that the record in the case was developed in a seriously flawed judicial proceeding.

Throughout the later proceedings, including the federal *habeas corpus* and civil rights litigation that occurred in early 2005 and the flurry of legislative activity in Congress on legislation for the "[r]elief of the parents of Theresa Marie Schiavo[,]"[166] it was clear that the Schindler family was litigating against a "conventional wisdom" rooted in attitudes about the "right to die." In *Schiavo*, it took the form of a series of presumptions about disputed facts, including:

(i) *Terri's condition.* Michael Schiavo, Terri's husband, took inconsistent positions concerning Terri's condition. During the medical malpractice case filed against her primary care physician and gynecologist,[167] Mr. Schiavo testified that "she does feel pain"[168] and would, on

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http://news.findlaw.com/hdocs/docs/schiavo/flagovexord03201.html.

[165] *See supra* text accompanying note 142 and accompanying text.

[166] Relief of the Parents of Theresa Marie Schiavo, Pub. L. No. 109-3, 119 Stat. 15 (2005). The original draft of the legislation was an amendment to the federal *habeas corpus* statute, 28 U.S.C. §2241 (2007). That amendment would have made it clear that persons enmeshed in disputed guardianship proceedings can be considered a "person in custody." As finally adopted, Public Law 109-3 granted specific subject matter jurisdiction to the United States District Court for the Middle District of Florida:

> to hear, determine, and render judgment on a suit or claim by or on behalf of Theresa Marie Schiavo for the alleged violation of any right of Theresa Marie Schiavo under the Constitution or laws of the United States relating to the withholding or withdrawal of food, fluids, or medical treatment necessary to sustain her life.

Pub. L. No. 109-3, § 1, 119 Stat. 15 (2005) (emphasis added).

[167] See text at notes 24-25.

[168] Direct testimony of Michael Schiavo, Medical Malpractice Case, *supra*, note 25, at p. 17, lines 15-19:

occasion, swallow.[169] By the time he had filed the petition to withhold nutrition and hydration, Michael Schiavo had changed his view. "Terri was beyond any meaningful rescue" after suffering a massive brain injury in 1990, and "she never had any hope of recovery."[170] The medical record, however, contained some evidence of cognitive function, including a reference to a situation in which Terri had responded verbally to a question posed by a physical therapist.[171]

(ii) *The rejection of neuroplasticity.* We will never know for certain whether the cessation of rehabilitation harmed Terri Schiavo's chances of recovery, but recent advances in neuroscience support her parents' claim that aggressive rehabilitation would have been helpful. These advances also support the contention that the condition of Terri's brain at death was attributable, at least in part, to lack of stimulation, rather than the initial injury.[172]

A. [A]nd I usually do a little bit of range of motion with her

Q. And while you're doing that, do you talk to her?

A. Yes, I am talking to her right now telling her it's okay

Q. She does't like it very much?

A. No, she doesn't. She does feel pain.

Id. at 23, lines 8-12:

Q. Does she express discomfort [during physical therapy]?

A. Yes. Yes, she does.

Q. How does she do that?

A. She'll moan and groan.

[169] *Id.* at 20, lines 14-19.

[170] Michael Shelden, *Her Soul Had Gone, Her Body Was Ready*, THE TELEGRAPH ONLINE, Oct. 30, 2006 (discussing an interview with Michael Schiavo).

[171] E-mail message from Patricia Campbell Andersen, counsel for the Schindler family during the hearings, to Robert A. Destro, Aug. 25, 2004 (on file with the author): "MediPlex Rehab Center in Bradenton, FL in January, 1991. Discharged in July, 1991. While there, Terri said "no" and "stop" during vigorous physical therapy . . . ."

[172] *See* Letter from Stephen J. Nelson, Chief Medical Examiner, 10th Judicial Circuit of Florida, to Jon R. Thogmartin, District 6 Medical Examiner 9 (June 8, 2005) (Neuropathology Report) in THOGMARTIN, *supra* note 4 at 20 ("Neuropathologic examination alone of the decedent's brain – or any brain, for that matter – cannot prove or disprove a diagnosis of persistent vegetative state or minimally conscious state.").

Both human and animal studies have shown that "the primary motor cortex (M1) can reorganise after a focal vascular lesion if there is motor skill retraining. In animals not trained after a stroke, there is a further reduction in the size of the hand representation in M1."[173]

(iii) *Lack of medical and neuroscientific understanding of the minimally conscious state.* At the time the *Schiavo* case was tried in the guardianship court, it was widely assumed that the brain, once injured, could not recover. Today, there is a far more extensive literature on this subject, and a far greater understanding of the organization and functioning of the brain. At the time of the *habeas corpus* proceeding in February 2005, this literature was available, and neuroplasticity was "generally accepted" in the scientific community. It is unclear why the courts rejected the family's pleas that experts be permitted to utilize appropriate, state-of-the-art, diagnostic imaging to get an accurate picture of Terri's brain functions, but it is safe to assume from the "heart-breaking detail" and empathy expressed by the judges in the various proceedings in early 2005 that, like Michael, they had concluded that Terri's life was "so impoverished and hopeless that [it was] judged not worth living."[174]

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[173] R.M. Bracewell, Editorial Commentary, *Neuroplasticity and Rehabilitation, Stroke: Neuroplasticity and Recent Approaches to Rehabilitation*, 74 JOURNAL OF NEUROLOGY NEUROSURGERY & PSYCHIATRY 1465 (2003).

[174] Richard S. Kay, *Causing Death for Compassionate Reasons in American Law*, 54 AM. J. COMP. L. (SUPP.) 693, 714 (2006) (internal citations omitted). The Florida courts provided just such detail in *Schiavo I*, stating as follows:

> The evidence is overwhelming that Theresa is in a permanent or persistent vegetative state. It is important to understand that a persistent vegetative state is not simply a coma. She is not asleep. She has cycles of apparent wakefulness and apparent sleep without any cognition or awareness. As she breathes, she often makes moaning sounds. Theresa has severe contractures of her hands, elbows, knees, and feet.
>
> Over the span of this last decade, Theresa's brain has deteriorated because of the lack of oxygen it suffered at the time of the heart attack. By mid 1996, the CAT scans of her brain showed a severely abnormal structure. At this point, much of her cerebral cortex is simply gone and has been replaced by cerebral spinal fluid. Medicine cannot cure this condition. Unless an act of God, a true

(iv) *The unfairness of her trial.* Both the federal courts and many post-mortem commentaries on the *Schiavo* case focused on the "proceedings" in the guardianship case. One writer even went so far as to state that:

> A thorough examination of the Terri Schiavo guardianship proceedings reveals that the judicial process, both substantively and procedurally, achieved a decision that was consistent with the specific facts of Mrs. Schiavo's case and Florida's established legal framework . . . . This conclusion is important because it challenges those claims of the Religious Right that attempted to undermine the credibility and legitimacy of the Florida judiciary.[175]

Each of these points assumes a) that the "specific facts of Mrs. Schiavo's case" were fully litigated; b) that the *conduct* of the trial was consistent with "Florida's established legal framework," and c) that a *habeas corpus* attack on the proceedings of a guardianship court was little more than an "attempt[ ] . . . to undermine the credibility and legitimacy of the Florida judiciary."[176] The goal of the Schindler family, by contrast, was to raise enough doubts about the fairness of the proceeding to make a plausible case for a new trial.[177] This would have been the outcome had a federal court granted the family's petition for a writ of *habeas corpus*[178] or, in the alternative, granted the new trial authorized by Congress in Public Law 109-3.[179]

> miracle, were to recreate her brain, Theresa will always remain in an unconscious, reflexive state, totally dependent upon others to feed her and care for her most private needs. She could remain in this state for many years.

In re Guardianship of Schiavo, 780 So. 2d 176, 177 (Fla. Ct. App. 2001) (*Schiavo I*) (internal citations omitted).

[175] Perry, *supra* note 160, at 555.

[176] Perry, *supra* note 160, at 555 (assuming that Bush v. Schiavo, 885 So. 2d 321 (Fla. 2004), *cert. denied*, 543 U.S. 1121 (2005), was correctly decided).

[177] *See* Petition for *Certiorari*, Bush v. Schiavo, 543 U.S. 1121 (2005) (No. 04-757), 2004 WL 2790640.

[178] Schiavo v. Greer, No. 8:05-CV-522-T-30TGW, 2005 WL 754121 (M.D. Fla. Mar 18, 2005), *vacated by* Schiavo *ex rel* Schiavo v. Greer, No. 8:05-CV-522-T-30TGW, 2005 WL 2240351 (M.D. Fla. Mar. 21, 2005).

[179] Relief of the Parents of Theresa Marie Schiavo, Pub. L. No. 109-3, 119 Stat. 15

VI. "THINKING LIKE A (GOOD) LAWYER": THE RULES OF PROFESSIONAL CONDUCT AND THE LAWYER'S OBLIGATION TO INVESTIGATE THE FACTUAL AND LEGAL PREDICATES ON WHICH THE "CONVENTIONAL WISDOM" IS BASED

A number of commentators have argued, in the words of Joshua Perry, for example, that criticism of the Florida courts was "imprecise and irresponsible because it fail[ed] to distinguish between the quality of the judicial process and the outcome of the judicial process."[180]

This is a rather strange criticism. The professional responsibility (or lack thereof) of any lawyer who serves as advocate or advisor (or both) in any civil or criminal case, including one as high-profile as *Schiavo*, is—and, ethically, must be—the starting point for an analysis of the lawyer's behavior.

A. The Duty to Make Only Good-Faith Claims

The first duty of the lawyer is to make an *independent, professional* judgment[181] concerning the merits of the case. This is so because Rule 3.1 of the American Bar Association's Model Rules of Professional Conduct provides that:

> A lawyer shall not bring or defend a proceeding, or assert or controvert an issue therein, unless there is a basis in law and fact for doing so that is not frivolous, which includes a good

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(2005). This Congressional Act granted specific subject matter jurisdiction to the United States District Court for the Middle District of Florida:

> to hear, determine, and render judgment on a suit or claim by or on behalf of Theresa Marie Schiavo for the alleged violation of any right of Theresa Marie Schiavo under the Constitution or laws of the United States relating to the withholding or withdrawal of food, fluids, or medical treatment necessary to sustain her life.

Id. at § 1, 119 Stat. 15.

[180] *See, e.g.*, Perry, *supra* note 160, at 620; *see also id.* at 589-90 nn.160 & 163 (recounting allegedly inflammatory comments by counsel for the Schindler family and Governor Bush).

[181] MODEL RULES OF PROF'L CONDUCT R. 2.1 (2006) ("In representing a client, a lawyer shall exercise independent professional judgment and render candid advice. In rendering advice, a lawyer may refer not only to law but to other considerations such as moral, economic, social and political factors, that may be relevant to the client's situation.").

> faith argument for an extension, modification or reversal of existing law. A lawyer for the defendant in a criminal proceeding, or the respondent in a proceeding that could result in incarceration, may nevertheless so defend the proceeding as to require that every element of the case be established.[182]

For many readers, and indeed for many of the judges assigned to hear Terri's case, the claim that Terri did not get a fair trial is somewhat counter-intuitive. The case did, after all, take nearly fifteen years to work its way through the courts. Nevertheless, the fact remains that *none* of the courts that actually considered the case were willing to consider the fair trial issue. Consider the following extract from the transcript of the oral argument in *Bush v. Schiavo*:

> CHIEF JUSTICE: Good morning, ladies and gentlemen, and welcome to the Florida Supreme Court. The first case this morning is Bush versus Schiavo. Are the parties ready? . . .
>
> [MR DESTRO:] Yes, Your Honor . . . .
>
> [CHIEF JUSTICE:] Before you get into your argument, the court would appreciate it if . . . you would address the separation of powers, first, with the privacy argument, and with whatever free time you have, you can argue the other issues.
>
> [MR DESTRO:] Thank you, Your Honor. May it please the Court. Terri Schiavo did not have [a fair trial or the benefit of] an independent [guardian *ad litem* represented by counsel].
>
> JUSTICE WELLS: Let's try to get into the argument on separation of powers . . . .[183]

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[182] MODEL RULES OF PROF'L CONDUCT R. 3.1. The two states in which I am admitted to the Bar, California and Ohio, have similar rules, as does the Florida State Bar, whose rules govern in all legal proceedings before the courts of the State of Florida.

[183] Transcript of Oral Argument, Bush v. Schiavo, 885 So. 2d 321 (Fla. 2004), *cert. denied*, 543 U.S. 1121 (2005). The transcript is available at http://www.wfsu.org/gavel2gavel/transcript/04-925.htm. The bracketed material was omitted from the transcript. Obvious misspellings of names have been corrected without

From my perspective as appellate counsel, this was an extraordinary (albeit expected) exchange. Lack of procedural due process during the trial was one of the only plausible legal theories on which a claim for relief could have been granted. Once the guardianship court had made its initial finding that Terri was in a "persistent vegetative state" and that she would not want to be maintained in that condition, the only way to attack those findings of fact was to attack the process by which they were found. Viewed from that perspective, "Terri's Law" and the Governor's Executive Order are similar to the non-judicial clemency proceedings that serve as the last hope of condemned criminals seeking to avoid the death penalty.

B. The Lawyer's Duty to a Client with Diminished Capacity

Representing an incompetent person is, even in the "best" of times, a difficult proposition. Rule 1.14(a) of the American Bar Association's Model Rules of Professional Conduct recognizes this problem when it advises that "the lawyer shall, as far as reasonably possible, maintain a normal client-lawyer relationship with the client[,]" even in cases where "a client's capacity to make adequately considered decisions in connection with a representation is diminished, whether because of minority, mental impairment or for some other reason."

In the case of an incompetent, laws governing guardianship, such as Florida Statutes Chapter 744, are the foundation of the lawyer's duty to seek the appointment of a guardian. Rule 1.14(b) provides:

> (b) When the lawyer reasonably believes that the client has diminished capacity, is at risk of substantial physical, financial or other harm unless action is taken and cannot adequately act in the client's own interest, the lawyer may take reasonably necessary protective action, including consulting with individuals or entities that have the ability to take action to protect the client and, in appropriate cases, seeking the appointment of a guardian *ad litem*, conservator or guardian.

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making note of the change.

Once that step is taken, the ethical terrain becomes treacherous indeed.

C. Who Is the Client? The Incompetent Ward or the Guardian?

Perhaps the most basic question in all of legal ethics is: *Who is the client*? In the case of an incompetent ward, the answer is clear: the client is the *ward*, not the guardian.[184] Because the guardian is competent and usually a close relation of the ward, the attorney must take great care to distinguish their respective interests.[185]

D. May an Attorney Represent a Guardian Who Has a Concurrent Conflict of Interest with the Interests of His or Her Ward?

The answer to this question is an unequivocal "no."[186] In order to understand its significance, however, it is necessary to describe the interests of the parties in the *Schiavo* case. Terri Schiavo was the incapacitated ward, and she was supposed to be the focus of the guardian's lawyer's duty of loyalty. In *Schiavo I*,[187] decided in 2001, Florida's Second District Court of Appeal had held that the difference of opinion concerning treatment "and the inheritance issue created the appearance of conflict" of interest between Michael, the guardian, and Terri, his ward. In early 2005, Terri's parents renewed this charge in their "Second Amended Petition to Remove Guardian," alleging that Michael Schiavo, her husband and guardian, effectively controlled Terri's representation, that he was represented by counsel throughout the proceeding, but that she was not, and that he had personal

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[184] *See* FLA. STAT. § 765.105(1) (2007) (providing for expedited judicial review when "[t]he surrogate or proxy's decision is not in accord with the patient's known desires or the provisions of this chapter"); § 744.3021(3) (allowing for the appointment of "an attorney to represent the interests of a minor at the hearing on the petition for appointment of a guardian.").

[185] MODEL RULES OF PROF'L CONDUCT R. 1.6, 1.7(f) (2006) (describing conflicts of interest). *See also* RESTATEMENT (THIRD) OF THE LAW GOVERNING LAWYERS §24 (2000).

[186] MODEL RULES OF PROF'L CONDUCT R. 1.7, 1.8, 1.14 (2006).

[187] 780 So. 2d 176, 178 (Fla. Dist. Ct. App. 2001).

and financial interests adverse to those of Terri.[188]

A 2005 filing in the Supreme Court of the United States, *Nault v. Mainor*,[189] presented the following question for review: "Whether a court violates due process when it appoints a guardian *ad litem* who has a clear conflict of interest and when it subsequently approves a settlement without considering the conflict of interest between the guardian and the incompetent person."[190] It is somewhat surprising that there is a difference of opinion among the courts that have considered the due process implications of a conflict of interest between a guardian and his or her ward. In Delaware, Hawaii, Mississippi, and Washington State, the absence of an adequate guardian is a denial of due process; but in Alabama, Florida, and Minnesota it is not.[191] The Rules of Professional Conduct, however, leave no doubt as to the answer to this question. Rules 1.7(a) and 1.8(g) prohibit representation in any case involving a "concurrent conflict of interest."[192] Rule 1.7(a) provides:

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[188] Second Amended Petition to Remove Guardian, *In re* Guardianship of Schiavo, No. 90-2908-GD-003, at 37-50 (Fla. Cir. Ct. 2000).

[189] Mainor v. Nault, 101 P.3d 308 (Nev. 2004), *cert. denied*, 546 U.S. 873 (2005). *See also* Petition for Writ of *Certiorari* to the Supreme Court of Nevada, Nault v. Mainor, 546 U.S. 873 (2005) (No. 05-82), 2005 WL 1660295.

[190] Petition for Writ of *Certiorari* to the Supreme Court of Nevada, Nault v. Mainor, 546 U.S. 873 (2005) (No. 05-82), 2005 WL 1660295, at *i.

[191] *Compare, e.g.*, Wilmington Medical Center, Inc. v. Severns, 433 A.2d 1047, 1049 (Del. 1981); Leslie v. Estate of Tavares, 984 P.2d 1220, 1231 (Haw. 1999); *In re* R.D. and B.D., 658 So. 2d 1378, 1383 (Miss. 1995); *and* Cochran v. Estrada, No. 46695-O-I, 2001 Wash. App. LEXIS 364, at *4 (Feb. 26, 2001); *with, e.g., In re* E.F., 639 So. 2d 639, 644 (Fla. Dist. Ct. App. 1994) (concluding due process does not require appointment of a guardian *ad litem*); *In re* Frederickson, 388 N.W.2d 717, 721 (Minn. 1986) (finding no due process violation from the failure to appoint a guardian); *and* Leigh v. Aiken, 311 So. 2d 444, 446 (Ala. Civ. App. 1975) (holding due process does not require appointment of a guardian *ad litem*). *See also In re* Pattison, 121 P.3d 423 (Kan. 2005) (suspending lawyer who served as guardian *ad litem* for children from the practice of law because he had developed a romantic relationship with their mother); *and In re* Guardianship of Walther, No. 20095, 2004 WL 1454464 (Ohio Ct. App. June 25, 2004) (removing attorney as guardian of the ward's estate because he represented the ward's son, who was serving as the guardian of the ward's person, and took actions on the son's behalf that were inconsistent with his duty of loyalty to the ward's estate).

[192] MODEL RULES OF PROF'L CONDUCT R. 1.7 and 1.8 (2006).

> (a) Except as provided in paragraph (b),[193] a lawyer shall not represent a client if the representation involves a concurrent conflict of interest. A concurrent conflict of interest exists if:
>
> (1) the representation of one client will be directly adverse to another client; or
>
> (2) there is a significant risk that the representation of one or more clients will be materially limited by the lawyer's responsibilities to another client, a former client or a third person or by a personal interest of the lawyer.

Rule 1.8(g) deals directly with the "Question Presented" in *Nault v.* Mainor,[194] and would not permit a lawyer to represent both the guardian and the ward if there is any sort of conflict of interest between them:[195]

> (g) A lawyer who represents two or more clients shall not participate in making an aggregate settlement of the claims of or against the clients, or in a criminal case an aggregated agreement as to guilty or nolo contendere pleas, unless each client gives informed consent, in a writing signed by the client. The lawyer's disclosure shall include the existence and nature of all the claims or pleas involved and of the participation of each person in the settlement.[196]

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[193] MODEL RULES OF PROF'L CONDUCT R. 1.7 (2006). Rule 1.7(b) provides:

> (b) Notwithstanding the existence of a concurrent conflict of interest under paragraph (a), a lawyer may represent a client if:
>
> (1) the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client;
>
> (2) the representation is not prohibited by law;
>
> (3) the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and
>
> (4) each affected client gives informed consent, confirmed in writing.

Id.

[194] *See supra* text accompanying note 190.

[195] *Accord* Carson P. *ex rel.* Foreman v. Heineman, 240 F.R.D. 456 (D. Neb. 2007) (finding attorney may serve as guardian *ad litem* and lawyer if there is no conflict of interest).

[196] MODEL RULES OF PROF'L CONDUCT R. 1.8 (2006). *Accord In re* Black, 883 So. 2d 956 (La. 2004) (disbarring attorney for conflict between his own interests and those of two vulnerable clients).

E. Does Florida Statutory Law Prohibit Conflicts of Interest Between Guardians and Wards Even If Florida Courts Refuse To Hold As a Matter of Florida Constitutional Law That a Conflict of Interest Between Guardian and Ward Creates a Due Process Violation?

Notwithstanding the Florida courts' willingness to permit conflicts of interest between guardians and wards, and, as we shall see, conflicts of duty between judges and litigants, the Florida Legislature has expressly forbidden such conflicts:

> (b) No judge shall act as guardian after this law becomes effective, except when he or she is related to the ward by blood, marriage, or adoption, or has maintained a close relationship with the ward or the ward's family, and serves without compensation . . . .
>
> (3) Disqualified persons. — No person who has been convicted of a felony or who, from any incapacity or illness, is incapable of discharging the duties of a guardian, or who is otherwise unsuitable to perform the duties of a guardian, shall be appointed to act as guardian . . . . *The court may not appoint a guardian in any other circumstance in which a conflict of interest may occur.*[197]

VII. APPLYING THE RULES: CAN A "COLORABLE" CASE BE MADE THAT TERRI SCHIAVO WAS DENIED A FAIR TRIAL IN THE "SUBSTITUTED JUDGMENT" CASE IN WHICH THE NATURE OF HER CONDITION AND HER INTENT TO REFUSE TREATMENT WERE LITIGATED?

It is axiomatic that "[a] fair trial in a fair tribunal is a basic requirement of due process,"[198] and that the adversarial nature of common law trials requires not only that the proceeding *be* fair, but also that "justice must [also] satisfy the *appearance* of justice."[199]

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[197] FLA. STAT. § 744.309(1)(b), (3) (2007) (emphasis added).

[198] *In re* Murchison, 349 U.S. 133, 136 (1955).

[199] Offutt v. United States, 348 U.S. 11, 14 (1954) (emphasis added).

In civil or criminal cases involving severely incapacitated individuals like Terri Schiavo, the law, the rules of legal ethics, and simple respect for the equal rights and human dignity of the individual require that all of the lawyers and judges involved in the proceeding satisfy themselves that there is no bias on the basis of "disability."[200] It should also be apparent by this point that any breach of ethics in the decision-making *process* will cast doubt on the effectiveness of the representation, the reliability of the fact-finding process, and the integrity of the judicial proceeding as a whole.

Florida courts have held that Florida's explicit right to privacy[201] guarantees the right of both competent and incompetent patients to make fully informed decisions to refuse medical treatments, including the assisted provision of food and water.[202] If the family members agree about the incompetent patient's wishes, and there is no dissent, the decision to discontinue artificial life support is a private medical decision that needs no court oversight.[203] If there are questions about the oral instructions of the incapacitated person, however, or if an interested party disagrees with the decision, "the surrogate or proxy may choose to present the question to the court for resolution" or "interested parties may challenge the decision of the proxy or surrogate."[204] When a dispute arose between Michael Schiavo and Terri's parents over cessation of treatment, Robert and Mary Schindler, acting on behalf of their daughter, presented the question to Judge Greer for review pursuant to Florida Law.[205]

A guardianship trial that contemplates an order to withhold or withdraw life-sustaining treatment will necessarily consider

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[200] *See* MODEL RULES OF PROF'L CONDUCT R. 1.14 (2006); MODEL CODE OF JUDICIAL CONDUCT Canon 2(B)(5), (6) (2006) (requiring special attention to elimination of bias on, among other grounds, "disability.").

[201] FLA. CONST. art. I, § 23. *See also* Code of Conduct of the Bar of England and Wales, 204, 305.1 (Bar Council 2004).

[202] *In re* Guardianship of Browning, 568 So. 2d 4 (Fla.1990); Satz v. Perlmutter, 379 So. 2d 359 (Fla. 1980) (discussing rights of competent patients).

[203] FLA. STAT. §§ 765.205, 765.305, 765.306, & 765.401 (2007).

[204] *In re* Guardianship of Browning, 568 So. 2d 4, 16 (Fla. 1990).

[205] Fla. Stat. § 765.401 (2007).

the evidence concerning the patient's condition, as well as evidence about the patient's attitudes about life and death, her beliefs, aspirations, relationships, and fears. Effective representation necessarily includes careful fact investigation, presentation of credible witnesses, active cross-examination, and presentation of direct medical evidence. Without it, the incompetent person's right to privacy can easily fall prey to imbalances in the relative experience, knowledge, or time commitment of the counsel who appear in the case.

Because of the nature of the conflicting interests involved when a family splits into warring camps in a contested proceeding over the termination of life-sustaining treatment, there are only two real ways to understand the dangers that ineffective assistance of counsel can pose to the interests of the incompetent ward. The first is to consult the voluminous case law on "ineffective assistance of counsel" that has arisen in the context of criminal law and procedure.[206] The other is to determine whether, and to what extent, it is possible under the facts of the specific case to make a colorable assertion that there is, in fact, a conflict of interest between the incompetent ward and those who purport to represent their interests.

An incompetent person is, by definition, incapable of contributing *in any way* to the preparation or presentation of the case, and cannot possibly observe, or complain about, any conflict of interest. That duty falls to others, namely, the lawyers who seek to represent any party to the proceeding, or the judge who must decide the case.[207]

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[206] *See generally Right to Counsel*, 37 GEO. L.J. ANN. REV. CRIM. PROC. 477, 496, 497 n.1558 (2008). *See also* Jenny Roberts, *The Mythical Divide Between Collateral and Direct Consequences of Criminal Convictions: Involuntary Commitment of "Sexually Violent Predators"*, 93 MINN. L. REV. 670 (2008) (discussing ineffective assistance of counsel in cases where a client is not informed of the consequences of his or her plea); Michael S. Vastine, *Is Your Client Prejudiced? Litigating Ineffective-Assistance-Of-Counsel Claims in Immigration Matters Arising in the Eleventh Circuit*, 62 U. MIAMI L. REV. 1063 (2008).

[207] MODEL RULES OF PROF'L CONDUCT R. 4.3, 4.4 (2006). MODEL CODE OF JUDICIAL CONDUCT Canon 3(B)(7) (2006) ("A judge shall accord to every person who has a legal interest in a proceeding, or that person's lawyer, the right to be heard according to law*. A judge shall not initiate, permit, or consider ex parte communications, or consider other communications made to the judge outside the presence of the parties concerning a

Terri Schiavo did not have *any* legal representation in Judge Greer's courtroom. Michael Schiavo was represented by experienced counsel in both his individual capacity and in his capacity as guardian. Various attorneys represented the Schindlers during the nearly fifteen years of litigation over this guardianship. Which of these counsel represented Terri?

The record shows that Terri was not officially noticed to appear for the proceedings, and she was not provided with a guardian *ad litem*[208] assisted by legal counsel. She had no way to confront witnesses against her, or to present her own evidence.

Worse, the record also shows that the court considered explicit allegations of conflict of interest between and among the parties: specifically, disputes over inheritance and over the proper course of treatment.[209] Because Terri had not left an advance directive, the first issue for the Florida courts to decide *should have been* the need for a guardian *ad litem* who would be represented by counsel.[210] Instead, the Second District Court of Appeal held that "there may be occasions when an inheritance could be a reason to question a surrogate's ability to make an objective decision."[211] As noted earlier, due to disagreement between Michael Schiavo and the Schindlers, and an appearance of conflict regarding the inheritance issue, the court held that "Michael Schiavo, as the guardian of Theresa, invoked *the trial court's jurisdiction to allow the trial court to serve as the surrogate decision-maker*."[212]

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pending or impending proceeding . . . .").

[208] The term "guardian ad litem" is defined in section 39.820(1) of the Florida Statutes in cases involving children as an attorney or other "responsible adult who is appointed by the court to represent the best interests of a child in a proceeding as provided for by law, including, but not limited to, this chapter, who is a party to any judicial proceeding as a representative of the child, and who serves until discharged by the court." FLA. STAT. § 39.820(1) (2007). *See also* FLA. PROB. R. 5.120 (2008) (providing a similar rule for probate proceedings).

[209] *See infra* text accompanying notes 214-15.

[210] FLA. STAT. §§ 744.301, 765.105, & 765.106 (2007).

[211] *In re* Guardianship of Schiavo, 780 So. 2d 176, 177-78 (Fla. Dist. Ct. App. 2001), *aff'd without opinion*, Schindler v. Schiavo *ex rel.* Schiavo, 789 So. 2d 348 (Fla. 2001) (emphasis added).

[212] *Id.* (emphasis added).

The importance of the italicized words above is not immediately apparent, so a bit of "unpacking" is in order.[213] Both the Probate Court and the District Court of Appeal agreed that *neither* Michael Schiavo *nor* the Schindlers could serve as Terri's surrogate because both stood to inherit from her estate, *and* there was a conflict between them regarding, among other things, the utility of rehabilitation, the quality of medical care, and Terri's attitudes toward cessation of life-sustaining treatment.[214] The Court of Appeal did, however, approve Michael's request as guardian *on Terri's behalf* "to allow the trial court to serve as the surrogate decision-maker."[215] This made the problem worse, not only for the Schindlers, who objected strenuously, but for Terri herself.

Neither Michael nor the Schindlers could serve as Terri's surrogate. There was no guardian *ad litem* at this point. Counsel for Michael and the Schindlers were also disqualified by virtue of their respective clients' conflicting interests. Who, then, acted on Terri's behalf? The record makes it clear that the Probate Court *itself* undertook the role of "surrogate decision-maker." As "surrogate decision-maker," Judge Greer became the *alter ego*, and legal representative, of Terri Schiavo.[216]

This, I contend, was clearly improper.[217] A judge must serve as a dispassionate trier of fact, and may not participate as a representative of any party.[218] If the court undertakes such a role, the trial becomes either an advisory process or an instrument of compulsion, rather than an adversary proceeding. This is why section 744.309(b) of the Florida Statutes expressly

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[213] A useful chart explaining the organization of the Florida court system can be found on the website of the Office of Justice Programs, U.S. Department of Justice, *State Court Organization 2004*, at 287, *available at* http://www.ojp.usdoj.gov/bjs/pub/pdf/sco04.pdf (last visited May 3, 2009).

[214] *See supra* note 187 and accompanying text.

[215] *See supra* note 187 and accompanying text.

[216] *Cf.* FLA. CODE OF JUDICIAL CONDUCT Canon 3(E)(1)(d)(iii) (requiring disqualification in any case in which a family member "within the third degree of relationship" to either the judge or his or her spouse has anything more than a "*de minimus* interest that could be substantially affected by the proceeding.").

[217] *See In re* T.W., 551 So. 2d 1186, 1190 n.3 (Fla. 1989).

[218] MODEL CODE OF JUDICIAL CONDUCT Canon 3(B)(5) (2007).

prohibits such a conflict of roles.[219] When a judge serves as either the advocate or surrogate for any of the parties who have an interest in a case pending before the court, he or she is no longer serving as a judge. In *In Re TW*, the Florida Supreme Court held that:

> Under no circumstances is a trial judge permitted to argue one side of a case as though he were a litigant in the proceedings. The survival of our system of justice depends on the maintenance of the judge as an independent and impartial decisionmaker. A judge who becomes an advocate cannot claim even the pretense of impartiality.[220]

For the Schindlers, the judge's conflict of interest made an already difficult case even harder to litigate. But the most serious impact of all fell upon Terri herself. She had *no* representation, legal or otherwise.

In *Sandstrom v. Butterworth*,[221] the United States Court of Appeals for the Eleventh Circuit (which includes Florida) recognized that an attorney's allegation that the judge has compromised his judicial independence "are among the most perplexing challenges that this Court encounters" and noted:

> This habeas corpus appeal presents just such a challenge. It involves one manifestation of the tension that exists between the courts' criminal contempt power and various tenets of constitutional due process. In the case at bar, petitioner's conviction for criminal contempt stands in conflict with an important principle of due process—the right to an impartial tribunal. To uphold the state court's adjudication of contempt would necessarily and significantly intrude upon that fundamental due process value. Alternatively, to vindicate the petitioner's right to an impartial tribunal would require imposing some limitation upon courts' traditionally broad contempt authority. Under the circumstances here, however, the potential impairment of the court's power is outweighed by unfairness to the petitioner. We, therefore, resolve the instant

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[219] *See supra* text accompanying note 197.

[220] *In re* T.W., 551 So. 2d at 1190 n.3.

[221] 738 F.2d 1200, 1201 (11th Cir. 1984).

conflict of values in favor of due process.[222]

The Florida courts apply precisely the same rule in other cases. In *Scott v. Anderson*,[223] the First District Court of Appeal noted:

> The familiar axiom "a man should not be judge of his own case" is of ancient origin, but it has apparently not yet found its way into Florida law to the extent necessary to provide distinct guidelines for deciding under what circumstances a judge must disqualify himself to adjudicate direct criminal contempt charges involving disrespect or criticism directed to that judge. Since the question is ultimately one of federal constitutional import, we must turn to, and be guided by the federal decisions.[224]

Because "[a]djudication before a neutral and unbiased tribunal stands as one of the most fundamental of due process rights[,]"[225] raising questions of bias is one of the most fundamental obligations of the first attorney to recognize the problem. But it is no easy task. The reported cases make it clear that charging the judge with bias during a trial can involve some personal risk to the attorney making the charge.

Although most lawyers and judges understand that "[t]hese are subtle matters, for they concern the ingredients of what constitutes justice,"[226] it is possible that some allegations of bias will be received by the judge, or by the judge's professional peers, as "highly personal aspersions" that "'strike 'at the most vulnerable and human qualities of a judge's temperament.'"[227]

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[222] *Id.*

[223] 405 So. 2d 228, 233 (Fla. Dist. Ct. App. 1981).

[224] *Id.*

[225] *Sandstrom*, 738 F.2d at 1211.

[226] Offutt v. United States, 348 U.S. 11, 14 (1954). Writing for the majority in *Offutt*, Justice Douglas observed that: "The record discloses not a rare flareup, not a show of evanescent irritation-a modicum of quick temper that must be allowed even judges. The record is persuasive that instead of representing the impersonal authority of law, the trial judge permitted himself to become personally embroiled with the petitioner." *Id.* at 17.

[227] Mayberry v. Pennsylvania, 400 U.S. 455, 466-67 (1971) (quoting Bloom v. Illinois, 391 U.S. 194 (1968), and distinguishing the case from Ungar v. Sarafite, 376 U.S. 575 (1964), in which comments to the judge did not rise to the level of a claim of bias).

In the reported cases cited here, the attorney's assertions of judicial bias were the basis of a contempt proceeding.

Contempt, however, is not the only personal, professional, or political risk for charging a sitting judge with bias or conflict of interest.[228] The *Schiavo* case provides an excellent example of a far more subtle and insidious constraint on a lawyer's willingness to confront a popular judge on behalf of an unpopular client or cause: political, social, or professional ostracism – or discipline.[229] A judge's unwillingness to make hard calls in high profile cases presents an analogous problem.[230]

In the *Schiavo* case, the local bench and bar were clearly invested in the "Death with Dignity" and "Judicial Independence" narratives of the case. The Clearwater Bar Association thought so highly of Judge Greer's "refus[al] to bend to the intense political assault the [*Schiavo*] case brought [upon him]" that it decided "[t]o celebrate [Judge] Greer's resolve" by creating a "George W. Greer Judicial Independence Award that would be awarded as part of its annual Law Day luncheon."[231] The message was not even subtle. Otherwise-legitimate assertions of judicial bias or conflict of interest in an attempt to ensure a fair trail for Terri Schiavo had been characterized by

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[228] See cases cited at notes 226 and 227 *supra.*

[229] *See generally,* Katherine R. Kruse, *Lawyers, Justice, and the Challenge of Moral Pluralism,* 90 MINN. L. REV. 389 (2005); David B. Wilkins, *Identities and Roles: Race, Recognition, and Professional Responsibility*, 57 MD. L. REV. 1502 (1998); Amy B. Letourneau, *Comment, Stropnicky v. Nathanson: Choosy Massachusetts Lawyers, Choose Your Fights With Care!*, 33 NEW ENG. L. REV. 125 (1998) (citing Richard J. Cohen, *Ruling in Discrimination Case "Must Be Opposed,"* MASS. LAW. WKLY., Apr. 14, 1997, at 10, which states that criticism of the result in *Stropnicky* "is an absolutely predictable result when an agency is a tool of political correctness.").

[230] *See* James Zagel & Adam Winkler, *The Independence of Judges*, 46 MERCER L. REV. 795 (1995); R. Samuel Paz, *Federal District Court Nomination Process: Smears of Controversy and Ideological Sentinels*, 28 LOY. L.A. L. REV. 903 (1995). *Cf.*, Stephen B. Bright, John Randolph Tucker Lecture: *Is Fairness Irrelevant?: The Evisceration of Federal Habeas Corpus Review and Limits on the Ability of State Courts to Protect Fundamental Rights*, 54 WASH. & LEE L.REV. 1 (1997); Erwin Chemerinsky, *Is It the Siren's Call?: Judges and Free Speech While Cases are Pending*, 29 Loy. L.A. L. Rev. 815 (1995).

[231] Aaron Sharockman, *Lawyers Honor Schiavo Judge*, ST. PETERSBURG TIMES, May 7, 2005, at 1, 2005 WLNR 7196893.

the Clearwater Bar Association as part and parcel of an "intense political assault" on judicial independence.

The selection of the first recipient of the "George W. Greer Judicial Independence Award" also sent a message about politically-correct judging. When it selected Judge W. Douglas Baird of the Sixth Judicial Circuit Court of Pinellas County, Florida, to receive the award, the Clearwater Bar Association conveyed a message that is as ethically stunning as it was legally unwise.

A review of the record of Judge Baird's actions in *Schiavo v. Bush*[232] shows that he took only one action in that case that merited the honor of being selected as the first recipient of the "George W. Greer Judicial Independence Award."" He entered a *summary judgment* on Michael Schiavo's claim that "Terri's Law" and the Governor's Executive Order asserting protective custody of Terri Schiavo after Judge Greer's order to remove the feeding tube had been executed were unconstitutional. Under Florida law,[233] the entry of summary judgment can mean only one thing: "the pleadings, depositions, answers to interrogatories, and admissions on file toge'ther with affidavits, if any, *conclusively show that there is no genuine issue as to any material fact . . .* ."[234]

This was the social and legal context in which counsel for the Schindlers moved to have Judge Greer recuse himself,[235] and in which they renewed their motions to have Michael Schiavo removed as guardian.[236] In both cases, the allegation that Terri

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[232] Schiavo v. Bush, No. 03-008212-CI-20, 2003 WL 25768817 (Fla. Cir. Ct. Nov. 7, 2003) (granting summary judgment), *aff'd*, 871 So. 2d 1012 (Fla. Dist. Ct. App. 2004), *aff'd*, Bush v. Schiavo, 885 So. 2d 321 (Fla. 2004), *cert. denied,* Bush v. Schiavo, 543 U.S. 1121 (2005).

[233] Fla. R. Civ. P. 1.510(c) (2009).

[234] Allenby & Associates, Inc. v. Crown "St. Vincent" Ltd., No. 4D08-1737, 2009 WL 1139244 (Fla. Dist. Ct. App. Apr. 29, 2009) (emphasis added).

[235] The Motion to Recuse Judge Greer was filed on April 10, 2001, and it was denied. *See* Kathy Cerminara & Kenneth Goodman, *Key Events in the Case of Theresa Marie Schiavo*, UNIVERSITY OF MIAMI ETHICS PROGRAMS: SCHIAVO CASE RESOURCES, *available at* http://www6.miami.edu/ethics/schiavo/timeline.htm (last accessed March 5, 2009).

[236] *Id.* at August 10, 2001. There were several attempts to remove Michael Schiavo as guardian. *See* William R. Levesque, Carrie Johnson & Anita Kumar, *Without a Ruling, the Wait Continues*, ST. PETERSBURG TIMES, Mar. 22, 2005, at 1A, *available at*

Schiavo and her parents were litigating before a tribunal whose process was irretrievably tainted was (and remains) supported by material facts and law that are very much in dispute.

The Florida courts, however, had made up their minds: the charges against Judge Greer and, by implication, the Florida courts themselves, were baseless. The Supreme Court of the United States addressed precisely this situation in *Mayberry v. Pennsylvania*, when it noted that "[n]o one so cruelly slandered is likely to maintain that calm detachment necessary for fair adjudication."[237] *Mayberry* has been read by the Eleventh Circuit as not "turn[ing] on proof of actual bias, but instead [it was] centered around a 'presumption' of bias."[238]

These facts, we argued, were sufficient to raise a colorable claim that Terri had been denied a fair trial in the original guardianship proceeding, and that she and her family were entitled to a new trial in which both her condition and her intent would be fully and fairly litigated. It should come as no surprise that we failed.[239] Although Congress provided in Public Law 109-3 for a trial *de novo* in the federal court, the United States District Court for the Middle District of Florida heard no evidence. In the words of the Eleventh Circuit: "the district court considered the federal constitutional claims *de novo*" by reviewing only the "prior proceedings" in the Florida courts,

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2005 WLNR 23899652.

[237] Mayberry v. Pennsylvania, 400 U.S. 455, 465 (1971).

[238] Sandstrom v. Butterworth, 738 F.2d 1200, 1210 (11th Cir. 1984) (citing United States v. Meyer, 462 F.2d 827, 842 (D.C. Cir.1972)).

[239] Schiavo *ex rel* Schiavo v. Greer, No. 8:05CV522T30TGW, 2005 WL 2240351 (M.D. Fla. Mar 21, 2005) (vacating the order rejecting the application of a writ of habeas corpus on the grounds that the trial court lacked jurisdiction over the case pursuant to the *Rooker-Feldman* doctrine, and that "Petitioners had failed to satisfy 28 U.S.C. §2254's requirement that Mrs. Schiavo was "in custody pursuant to the judgment of a State court."). After Congress adopted Pub. L. No. 109-3, 119 Stat. 15 (2005), the United States District Court for the Middle District of Florida denied a temporary restraining order on, among other grounds, a determination that the *status quo* had changed when the feeding tube was removed pursuant to Judge Greer's order. Schiavo *ex rel* Schindler v. Schiavo, 358 F. Supp. 2d 1161 (M.D. Fla. 2005), *aff'd* Schiavo ex rel. Schindler v. Schiavo, 403 F.3d 1223 (11th Cir. 2005) (affirming denial of temporary restraining order on the grounds that trial court's finding that parents had failed to demonstrate substantial case on merits of their claim was not abuse of discretion); 403 F.3d 1289 (11th Cir. 2005) (rejecting claims on the merits), *cert. denied*, 544 U.S. 957 (2005).

"and made its own independent evaluation of them."[240]

VIII. CONCLUSION

The burden of this article was not to disprove any of the points made by either Michael Schiavo or critics of those who sought, however unsuccessfully, to defend Terri Schiavo's interests. Though my criticism of the defective process that led to the final order to withdraw nutrition and hydration might be taken to engage that question, my purpose here is far more limited. I am more than satisfied to make the point that *nobody* knows precisely what Terri Schiavo's cognitive condition was at the moment her PEG tube was withdrawn. Though I have not examined the record in the Eluana Englaro case, I strongly suspect that this datum was missing in her case as well.

Armed with this information, the analogy to a capital case is clear. All lawyers who have studied the "great writ" of *habeas corpus* should be willing to concede that proceeding seeking *habeas corpus* in a guardianship case would (or should) not need to question any of the specific findings in order to state a claim for a new trial. It need only make a showing that the process errors in the guardianship case were so serious that the record *and the proceeding itself* were tainted by a denial of due process.

Like an involuntary commitment or a capital punishment case, the discontinuation of assisted feeding constitutes a deprivation of life, liberty, and property interests. Unless one is willing to assert—contrary to emerging scientific evidence—that *all* persons in a persistent vegetative state have lost the ability to respond cognitively to a variety of stimuli, advances in science require attorneys and judges to become even more scrupulous in their attention to the preservation of procedural due process rights.[241] The incapacitated person whose life and liberty interests are being curtailed with state approval has "a right to the effective assistance of counsel at all judicial proceedings which could result in a limitation on that person's liberty."[242]

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[240] *Schiavo ex rel.* Schindler, 403 F.3d at 1228.

[241] Chalk v. Florida, 443 So. 2d 421, 422 (Fla. Dist. Ct. App. 1984).

[242] *Id.*

Not surprisingly, the conventional wisdom that informs so much of the post-*Schiavo* case commentary is (once again) wrong. Terri Schiavo's case was never about "politicized religious forces" or nefarious attempts by the religious right to create a "culture war flashpoint." It was about whether a person with a traumatic brain injury could get a fair trial in a Florida court. Had she been a condemned criminal, the outcome—and the tenor of the discussion—would have been very different.

And thus, this article ends with the observation with which it began. Read together, the ethics of both law and medicine thus lead inexorably to the conclusion that the boundary between law and medicine is defined by the consistent application of a rule of reason to the facts and circumstances of each case. Because duty is our common calling, a professional responsibility (or "duty") model provides a powerful and precision-crafted lens through which to examine *any* decision, act, or omission by a legal or medical professional.

A good lawyer investigates the facts before drawing a conclusion, addressing the court or a witness, or making a legal argument. A good physician, neuroscientist, or allied health professional does precisely the same thing in the medical or research setting. And a well-informed judge insists that both professions do "right" by the patient whose welfare rests in their hands. Neither profession need worry about intrusion into the respective spheres of the other—or into the privacy rights of patients with consciousness disorders—unless there is some professional, ethical, or process lapse that creates probable cause to suspect that such a violation has taken place.

There were several such violations in the *Schiavo* case. The operative language of Public Law 109-3 confers jurisdiction on the United States District Court for the Middle District of Florida for the sole purpose of holding a trial *de novo* "[f]or the relief of the parents of Theresa Marie Schiavo." Like any trial *de novo*, its outcome would turn on the facts presented at the new trial. Like Lord Browne-Wilkinson in *Bolitho v. City and Hackney Health Authority*,[243] Congress and the President were

[243] Bolitho v. City and Hackney Health Auth., [1998] A.C. 232 (H.L.).

not bound to hold that the parties to a state court proceeding can escape judgment for acts that were not reasonable "just because [of] evidence from a number of medical [and legal] experts who are genuinely [of the opinion] that the [defendants' legal procedures,] treatment or diagnosis accorded with sound medical [or legal] practice . . . ."[244] Whatever the opinion of the leading experts might have been during the fifteen-year course of the *Schiavo* litigation, advances in neuroscience now demonstrate conclusively that their opinions on which the Florida courts relied were based on incomplete, and sometimes irrelevant, diagnostic techniques.

And so, I close this article with an admonition for both legal and medical professionals. Ethics requires taking personal responsibility for one's actions. Cases involving persons with traumatic brain injuries require that lawyers, judges, and witnesses produce a record that contains more than enough information to withstand a charge that the injured person's condition has been clearly and accurately stated. The record must demonstrate that the attorneys understand the range of medical and scientific opinion concerning the patient's conditions and the availability of diagnostic options tailored to that condition. In order for the case to have been fully and fairly litigated, there must be no meaningful lapses in the pleadings, discovery process, motions practice, trial, or appellate procedures and briefs.

If one can do all of that, and can prove that the actions taken are reasonable under the circumstances, there is no way in the world that *anyone* could make a plausible claim that the patient's case was tainted by an ineffective attorney or a biased judge. The facts would speak for themselves.

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[244] *Id.* The bracketed material in the quotation indicates the author's changes from Lord Browne-Wilkinson's original text. Although *Bolitho* involved only the assertion that the court is bound by the opinions of medical experts that the specific "treatment or diagnosis accorded with sound medical practice," Lord Browne-Wilkinson's point is, in my view, far broader.

† *Acknowledgments*:
I would like to thank my former client, Governor Jeb Bush, for his confidence and words of encouragement before the oral argument in the Florida Supreme Court, and each of my co-counsel in the various stages of the *Schiavo* litigation: Kenneth L. Connor, Esq., of Leesburg, Virginia, and Camille Godwin, Esq., of Tampa, Florida, with whom I worked on *Schiavo v. Bush* and the petition for *certiorari* filed on behalf of Governor Bush; David Gibbs, Esq., Barbara Weller, Esq., Patricia Campbell, Esq., and Matthew J. Davis, Esq., of Tampa, Florida, who served as lead counsel in the guardianship and *de novo* petition in the federal case; Walter Weber, Esq., of Washington, D.C., and Philip Kiko, Esq., and his staff counsel at the House Judiciary Committee, whose knowledge and experience on Capitol Hill (and the unanimous consent to the bill in the Senate engineered by Senators Rick Santorum, Edward Kenney, and Tom Durkin) made the federal legislation possible. All deserve credit for their hard work, understanding, and good humor under very trying conditions. Special thanks are reserved for my spouse, Brenda, and my children, Gina and Mark, whose patience and support during the final stages of the case made the pressure of "litigating at light speed" bearable.

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COMMENT

Expanding *Atkins* and *Roper*: A Diagnostic Approach to Excluding the Death Penalty As Punishment for Schizophrenic Offenders

I. INTRODUCTION

This comment is written at a time when citizens of the United States, as well as the Supreme Court, are questioning the benefits of capital punishment and the underlying foundation of death penalty jurisprudence. This reevaluation of capital punishment comes to the forefront as a result of many injustices that have been made public in recent years.[1] In recent years, many issues have been and continue to be discussed, such as concerns about the innocence of those sentenced to death, who should be subject to the death penalty, and what process is due to defendants prior to the death sentence being imposed upon them.[2] This comment will address the second of these issues; specifically, it will address whether or not individuals suffering

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[1] In the United States, there have been 233 post-conviction DNA exonerations, 168 of which have occurred since 2000. Innocence Project, Facts on Post-Conviction DNA Exonerations, http://www.innocenceproject.org/content/351.php (last visited Mar. 2, 2009). Seventeen of the individuals exonerated through DNA evidence served time on death row. *Id.* For a suspenseful account of the exoneration of Ron Williamson and Dennis Fritz, see JOHN GRISHAM, THE INNOCENT MAN (2006).

[2] *See supra* note 1; Panetti v. Quarterman, 127 S. Ct. 2842, 2863 (2007) (finding state court failed to provide delusional defendant with Constitutional procedures with respect to claim of incompetency to be executed); Roper v. Simmons, 543 U.S. 551, 571 (2005) (categorically excluding juveniles from the death penalty); Atkins v. Virginia, 536 U.S. 304, 321 (2002) (categorically excluding mentally retarded individuals from the death penalty).

from schizophrenia should be subject to capital punishment.

Today, scientific advances are having a significant impact on the outcome of criminal cases,[3] and as a result of technological advances, researchers are making great strides in understanding the human mind and the impact mental illness has upon the human brain.[4] In the past six years, the Supreme Court has held that individuals suffering from mental retardation and juveniles under the age of eighteen are categorically excluded from the death penalty.[5] These recent decisions, along with advances in technology, have subjected the issue of whether capital punishment is appropriate for those suffering from severe mental illness, which includes schizophrenia, to much scholarly debate.[6] The purpose of this comment is to demonstrate that capital punishment for individuals suffering from

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[3] *See supra* note 1. DNA Profiling, also known as DNA fingerprinting, was first recognized in the 1980's for forensic use. DNA AND THE CRIMINAL JUSTICE SYSTEM: THE TECHNOLOGY OF JUSTICE 27 (David Lazer, ed., 2004). It allows DNA extracted from crime scene samples of blood, hair, saliva, or semen to be compared with the DNA of suspects. *Id.* at 27-28. Because of the distinct nature of each individual's DNA sequencing, the probability of making an erroneous match is slight. *Id.* at 39-41. As a result, DNA evidence has emerged as a near failsafe method of identification. *Id.* at 50-52.

[4] *See* Wiepke Ċahn et al., *Brain Volume Changes in First Episode Schizophrenia: A 1-Year Follow-Up Study*, 59 ARCHIVES OF GEN. PSYSCHIATRY 1002, 1002-10 (2002) (finding loss of gray brain matter progressive and related to disease process and antipsychotic medications in individuals with schizophrenia); B.J. Casey, Jay N. Giedd, & Kathleen M. Thomas, *Structural and Functional Brain Development and Its Relation to Cognitive Development*, 54 BIOLOGICAL PSYCHOLOGY 241, 241-57 (2000) (illustrating how MRI and fMRI scans can be used to map changes in the human brain as a function of cognitive and behavioral development). *See, e.g.*, Cynthia Shannon, et al., *Human Dysbindin DTNBP1 Gene Expression in Normal Brain and in Schizophrenic Prefrontal Cortex and Midbrain*, 61 ARCHIVES OF GEN. PSYCHIATRY, 544, 544-55 (2004); Nat'l Inst. of Health & Nat'l Inst. of Mental Health Info. About Mental Illness and the Brain: The Science of Mental Illness, http://science.education.nih.gov/supplements/nih5/Mental/guide/info-mental-a.htm (last visited Mar. 3, 2009).

[5] *Roper*, 543 U.S. at 578; *Atkins*, 536 U.S. at 321.

[6] *See, e.g.*, Ronald J. Tabak, *Executing People With Mental Disabilities: How We Can Mitigate an Aggravating Situation*, 25 ST. LOUIS U. PUB. L. REV. 283 (2006); MICHAEL MELLO, *Executing the Mentally Ill: When is Someone Sane Enough to Die?*, 22 CRIM. JUST. 30 (2007); Ronald J. Tabak, *Mental Disability and Capital Punishment a More Rational Approach to a Disturbing Subject*, 34 HUM. RTS. 5 (2007); Laurie T. Izutsu, *Applying* Atkins v. Virginia *to Capital Defendants With Severe Mental Illness*, 70 BROOK. L. REV. 995 (2005).

schizophrenia at the time of the offense is cruel and unusual under the Eighth Amendment[7] for the same reasons that capital punishment for individuals suffering from mental retardation is cruel and unusual.

Inherent in the Eighth Amendment's ban on cruel and unusual punishment is the longstanding "principle of proportionality,"[8] the concept that the harshest punishments should be reserved for those defendants who commit the worst and most heinous crimes.[9] When deciding whether a punishment is "cruel and unusual," the Supreme Court of the United States has long recognized that the Eighth Amendment requires examining the "evolving standards of decency" of society at the time of imposition.[10] The "evolving standards of decency" test is two-pronged.[11] Under the first prong, the Court considers "objective factors to the maximum possible extent."[12] According to the Court, these objective factors include both state and federal legislative acts as well as the voting trends of juries; however, the Court additionally considers various other factors such as the advancement of penological goals and the mental limitations of

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[7] U.S. CONST. amend. VIII ("Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.").

[8] The language of "cruel and unusual punishment" that appears in the Eight Amendment was derived from the English Bill of Rights. Furman v. Georgia, 408 U.S. 238, 316 (1972) (Marshall, J., concurring). This language was originally incorporated into the English Bill of Rights as a legislative response to judicial overreaching in England during the late 1600's when several defendants were sentenced to punishments which were grossly disproportionate to the crimes they committed. STUART BANNER, THE DEATH PENALTY: AN AMERICAN HISTORY 232 (2002).

[9] *See* Weems v. United States, 217 U.S. 349, 365, 371-73, 380-81 (1910) (holding punishment was cruel and unusual because it was widely disproportionate to the crime). *See also* Furman, 408 U.S. at 331 (Marshall, J., concurring) (stating "a penalty may be cruel and unusual because it is excessive and serves no valid legislative purpose"). This principle is reflected in ancient texts, such as the Bible and the Magna Carta, which have withstood the test of time. BANNER, *supra* note 8, at 232. *See also Leviticus* 18:20 (. . . "eye for eye, tooth for tooth" . . .).

[10] Trop v. Dulles, 356 U.S. 86, 101 (1958).

[11] Roper v. Simmons, 543 U.S. 551, 564 (2005); Atkins v. Virginia, 536 U.S. 304, 312 (2002).

[12] *Atkins*, 536 U.S. at 312 (quoting Harmelin v. Michigan, 501 U.S. 957, 1000 (1991)). *See also* Rummel v. Estelle, 445 U.S. 263, 274-75 (1980).

offenders.[13] The second prong of this test requires the Court to utilize its own judgment in assessing whether or not the death penalty "comports with the basic concept of human dignity at the core of the [Eighth] Amendment."[14] What factors are considered under each prong and how much weight is given to each is unclear; considerations under each of these prongs appear to be intertwined.[15]

When analyzing whether a punishment is cruel and unusual, the Court considers whether the penological goals of the death penalty can be achieved through the execution of the individual.[16] According to the Court, capital punishment serves two primary social purposes: 1) retribution and 2) deterrence of capital offenses by potential offenders.[17] The Court has stated that the punishment imposed upon an individual "cannot be so totally without penological justification that it results in the gratuitous infliction of suffering."[18]

II. The History of Capital Punishment in the United States

A. Laying the Foundation for Challenging the Death Penalty under the Eighth Amendment

In order to properly discuss the issue upon which this comment focuses, it is important to understand the curvy path the United States Supreme Court's capital punishment jurisprudence has taken. To put the issue presented in context, one must first examine a few landmark cases that have helped

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[13] Gregg v. Georgia, 428 U.S. 153, 180-82 (1976). *See also Atkins*, 536 U.S. at 312 (stating that the "clearest and most reliable objective evidence of contemporary values is the legislation enacted by the country's legislatures" (quoting Penry v. Lynaugh, 492 U.S. 302, 331 (1989))).

[14] *Gregg*, 428 U.S. at 182 (citing *Trop*, 356 U.S. at 100). *See, e.g.*, *Roper*, 543 U.S. at 564; *Atkins*, 536 U.S. at 312 (quoting Coker v. Georgia, 433 U.S. 584, 597 (1977)).

[15] *See Roper*, 543 U.S. at 564-78; *Atkins*, 536 U.S. at 318-20.

[16] *See, e.g.*, *Gregg*, 428 U.S. at 183; Furman v. Georgia, 408 U.S. 238, 342-54 (1972) (Marshall, J., concurring).

[17] *Roper*, 543 U.S. at 571 (quoting *Gregg*, 428 U.S. at 183).

[18] *Gregg*, 428 U.S. at 183.

shape the current state of capital punishment in the United States.

Decisions of the Supreme Court interpreting the Eighth Amendment to the United States Constitution were virtually non-existent prior to 1962 when the Court incorporated the Eighth Amendment to the states through the Fourteenth Amendment's Due Process Clause.[19] Before 1962, there were only two decisions on record expressly discussing and interpreting the Eighth Amendment, both of which ultimately found legally sanctioned punishments "cruel and unusual" because the sentence was disproportionate to the crime committed.[20] These two cases involved non-capital crimes but paved the way for later challenges to the death penalty.

The first case expressly challenging a sentence as cruel and unusual under the Eighth Amendment was *Weems v. United States*.[21] In *Weems*, the Supreme Court overturned a sentence of fifteen years hard labor imposed against a United States official convicted of falsifying minor government documents.[22] Weems' punishment would not have been considered "cruel and unusual" at the time the Constitution was drafted in 1789;[23] however, in 1910, when *Weems* was decided, the Court was of the impression that Weems' sentence amounted to "cruel and unusual punishment" under the Eighth Amendment because his sentence was grossly disproportionate to the crime he committed.[24] In so holding, the Court stated that the Eighth Amendment ought not be "fastened to the obsolete, but may acquire meaning as public opinion becomes enlightened by a humane justice."[25]

In 1958, the Court directly addressed the interpretation of

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[19] Robinson v. California, 370 U.S. 660, 666-67 (1962) (finding a sentence of ninety days in prison for being addicted to narcotics "cruel and unusual").

[20] Trop v. Dulles, 356 U.S. 86 (1958); Weems v. United States, 217 U.S. 349 (1910).

[21] 217 U.S. 349 (1910).

[22] *Id.* at 357-58, 382.

[23] Because at that time, more tortuous sentences such as burning at the stake and dissection were imposed. Furman v. Georgia, 408 U.S. 238, 264-65 (1972) (Brennan, J., concurring).

[24] *Weems*, 217 U.S. at 382.

[25] *Id.* at 378.

the Eighth Amendment in *Trop v. Dulles*.[26] In *Trop*, the Court overturned a sentence of expatriation for the crime of desertion as cruel and unusual.[27] In arriving at this judgment, a plurality of the *Trop* court set forth what has come to be known as the standard guiding the Court's interpretation of the Cruel and Unusual Punishment Clause: the Eighth Amendment "must draw its meaning from the evolving standards of decency that mark the progress of a maturing society."[28] The *Trop* Court's deference to "evolving standards of decency" became the Court's framework for later deciding several landmark capital punishment cases.[29]

B. Challenging the Death Penalty As Cruel and Unusual Under the Eighth Amendment

In 1972, when the Court finally had the opportunity to consider, in *Furman v. Georgia,* whether the death penalty was cruel and unusual under the Eighth Amendment when no standards were in place to guide the jury's discretion in sentencing, the Court's reliance on the "evolving standards of decency"

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[26] 356 U.S. 86 (1958).

[27] *Id.* at 101, 104.

[28] *Id.* at 101. The "evolving standards of decency" framework is elastic. Justice Thurgood Marshall best illustrated this elasticity when he stated that a sentence that was acceptable at one point in history "is not necessarily permissible today." *Furman*, 408 U.S. at 329 (1972). This elasticity is evidenced by the waxing and waning of the Supreme Court's decisions in the years since *Furman* was decided. *See infra* note 29.

[29] *See. e.g.*, Roper v. Simmons, 543 U.S. 551 (2005) (holding that the Eighth Amendment barred execution of juveniles under the age of eighteen); Atkins v. Virginia, 536 U.S. 304 (2002) (holding that the Eighth Amendment barred capital punishment for mentally retarded defendants); Penry v. Lynaugh, 492 U.S. 302 (1989) (finding "evolving standards of decency" did not demand barring execution of mentally retarded defendants); Stanford v. Kentucky, 492 U.S. 361 (1989) (holding the Eighth Amendment did not bar the execution of sixteen or seventeen year olds); Thompson v. Oklahoma, 487 U.S. 815 (1988) (banning the execution of juveniles fifteen years of age or younger); Ford v. Wainwright, 477 U.S. 399 (1986) (holding that "insane" criminals could not be executed); Enmund v. Florida, 458 U.S. 782 (1982) (banning execution for accomplices to murder who did not aim bodily harm or demonstrate reckless indifference to human life); Coker v. Georgia, 433 U.S. 584 (1977) (outlawing the death penalty for rape of an adult); Gregg v. Georgia, 428 U.S. 153 (1976) (lifting the moratorium on the death penalty where statutes met the dictates of *Furman*); Furman v. Georgia, 408 U.S. 238 (1972) (per curiam) (Douglas, J., concurring) (holding death penalty unconstitutional as applied).

framework led to a moratorium being placed on the death penalty.[30] The *Furman* dissenters, however, were quick to point out that this holding did not prohibit capital punishment "for all crimes and under all circumstances" and that states were free to reevaluate and revise their capital statutes to comport with the majority's holding.[31] The moratorium on the death penalty did not last long. Numerous states subsequently revised their statutes to comply with the suggestions of the *Furman* dissenters,[32] and four years after *Furman* was decided, the Supreme Court found that Georgia's revised capital statutes passed constitutional scrutiny.[33]

Once the moratorium on the death penalty was lifted in 1976, an onslaught of cases challenging the constitutionality of the death penalty under the Eighth Amendment rapidly ensued.[34] In deciding these cases, the Court adhered to the view that the death penalty should be reserved for the worst of the worst defendants.[35] In 2002, the Court decided *Atkins v. Virginia*,[36] a case that addressed an issue closely analogous to the issue addressed in this comment. In *Atkins*, the Court took a different approach to the principle of proportionality. The Court did not find that Atkins's sentence was disproportionate to the crime he committed; rather, it found that the death sentence was excessive for certain type of offenders: mentally retarded of-

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[30] *Furman*, 408 U.S. at 242.

[31] *Id.* at 375, 396-405 (Burger, J., dissenting); *see also id.* at 414 (Powell, J., dissenting).

[32] Gregg v. Georgia, 428 U.S. 153, 180 (1976). At the time *Gregg* was decided at least 35 states had revised or enacted new death penalty statutes. *Id.*

[33] *Id.* at 207.

[34] *See supra* note 29.

[35] *See* Zant v. Stephens, 462 U.S. 862, 877 (1983) ("[Aggravat[ors] must genuinely narrow the class of persons eligible for the death penalty and must reasonably justify the imposition of a more severe sentence on the defendant compared to others found guilty of murder."); Godfrey v. Georgia, 446 U.S. 420, 433 (1980) (invalidating sentence where there was "no principled way to distinguish this case, in which the death penalty was imposed, from the many cases in which it was not."); *Gregg*, 428 U.S. at 184 (stating that death "may be the appropriate sanction in extreme cases is an expression of the community's belief that certain crimes are themselves so grievous an affront to humanity that the only adequate response may be the penalty of death.").

[36] 536 U.S. 304 (2002).

fenders.[37]

Applying the "evolving standards of decency" analysis, the Court ultimately concluded that the execution of mentally retarded defendants was cruel and unusual under the Eighth Amendment.[38] The *Atkins* court found that "national consensus" established that offenders with limited mental capacity are not among the worst of the worst offenders.[39] Additionally, the Court found that the cognitive and behavioral limitations of persons with mental retardation, as well as their inability to control impulses, established that this population was less culpable than other individuals who engaged in criminal conduct.[40] Therefore, sentencing these individuals to death could not advance the two primary penological goals, retribution and deterrence.[41] Applying this rationale, the Court held three years later, in 2005, that the Eighth Amendment barred the execution of juveniles under the age of eighteen.[42] As a result of these two decisions, defendants with mental retardation and defendants under the age of eighteen are categorically excluded from eligibility for the death penalty.

III. Categorical Exclusion of the Mentally Retarded and Juveniles from Capital Punishment

In order to put the issue upon which this comment focuses in perspective, the *Atkins* and *Roper* decisions must first be analyzed in detail.

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[37] *Id.* at 321.

[38] *Id.*

[39] *Id.* at 316. This decision was evidence that standards of decency indeed evolved because *Penry,* which was decided approximately thirteen years earlier, found that national consensus at that time did not establish that standards of decency required the barring of the death penalty for mentally retarded defendants. Penry v. Lynaugh, 492 U.S. 302, 340 (1989).

[40] *Atkins,* 536 U.S. at 318-21.

[41] *Id.*

[42] Roper v. Simmons, 543 U.S. 551, 578 (2005).

A. Atkins v. Virginia[43]

Atkins involved the case of Daryl Renard Atkins who was sentenced to death after being convicted of "abduction, armed robbery, and capital murder."[44] In the sentencing phase of Atkins's trial, the prosecution presented evidence proving two aggravating factors: 1) "future dangerousness" and 2) "vileness of the offense."[45] Atkins's defense attorney presented mitigating evidence consisting of the testimony of a forensic psychologist who testified that Atkins had an IQ of fifty-nine; therefore he was "mildly mentally retarded."[46] On appeal, the Virginia Supreme Court affirmed Atkins's conviction by relying on the United States Supreme Court's holding in *Penry v. Lynaugh*,[47] however, the dissent in the Virginia Supreme Court decision concluded that "the imposition of the sentence of death upon a criminal defendant who has the mental age of a child between the ages of 9 and 12 is excessive."[48] Based upon the concerns of the dissenters and upon evidence of a shift in "the state legislative landscape" that had occurred in the thirteen years since it had first heard *Penry*, the United States Supreme Court granted certiorari to re-examine whether the execution of individuals with mental retardation violates the Eight Amendment's ban on "cruel and unusual punishment."[49]

The Court, in deciding *Atkins*, applied the evolving standards of decency test. Under the first prong, the Court considered the "objective factors." The Court found compelling that in 1988, when re-instating the death penalty for federal crimes, Congress expressly barred the execution of persons who were

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[43] 536 U.S. 304 (2002).

[44] *Id.* at 307.

[45] *Id.* at 307-08. The prosecution proved this by presenting evidence of Atkins's previous convictions, his criminal record, and documentation contained in the trial record which included the autopsy report, as well as by introducing photographs of the victim's body. *Id.* at 308.

[46] *Id.* at 308-09.

[47] Penry v. Lynaugh, 492 U.S. 302, 340 (1989) (holding the Eighth Amendment did not bar the execution of mentally retarded defendants).

[48] *Atkins*, 536 U.S. at 310.

[49] *Id.*

mentally retarded.[50] Furthermore, eighteen state legislatures had barred the execution of mentally retarded persons, another fourteen States had rejected capital punishment altogether, and in the states retaining capital punishment for mentally retarded individuals, only five defendants with an IQ of less than seventy had been executed since the Court's decision in *Penry*.[51] Additionally, the Court noted the general consensus among religious groups, social and professional organizations, and the international community that the execution of mentally retarded offenders was unethical.[52] The Court found these facts to constitute evidence that society now viewed mentally retarded defendants as "less culpable than the average criminal."[53]

The Court identified two other principal reasons for categorically exempting this population from the death penalty. First, the Court found that the two primary penological goals of the death penalty, retribution and deterrence, were unlikely to be achieved by executing mentally retarded defendants.[54] The Court stated that unless the imposition of the death penalty contributed meaningfully to either of these goals, it "is nothing more than the purposeless and needless imposition of pain and suffering."[55] The Court noted that retribution, or the concept of "just deserts," is conditioned upon an individual's culpability.[56] The Court stated "[i]f the culpability of the average murderer is insufficient to justify the most extreme sanction available to the State, the lesser culpability of the mentally retarded offender surely does not merit that form of retribution."[57] The Court

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[50] *Id.* at 314.

[51] *Id.*at 315-16.

[52] *Id.* at 316-17 n.21.

[53] *Id.* at 304.

[54] *Id.* at 318-20. The Court has long recognized "retribution and deterrence," as the primary societal goals sought to be achieved by the death penalty. Gregg v. Georgia, 428 U.S. 153, 183 (1976).

[55] *Atkins,* 536 U.S. at 319 (quoting Enmund v. Florida 458 U.S. 782, 798 (1982)). The Court stated that it has routinely sought to ensure that the death penalty is reserved for only the most culpable and most deserving of punishment. *Id. See* Godfrey v. Georgia, 446 U.S. 420 (1980) (reversing death sentence for defendant whose crimes were no more deserving of death than others guilty of murder).

[56] *Atkins,* 536 U.S. at 319.

[57] *Id.* at 319 (citing *Godfrey*, 446 U.S. at 433).

found that this population, because of their cognitive and behavioral limitations, such as their "diminished ability to understand and process information, to learn from experience, to engage in logical reasoning, or to control impulses," was not likely to be deterred since their crimes are often not the result of "premeditation and deliberation."[58]

Second, the Court was concerned that mentally retarded offenders were likely to be subjected to the death penalty even though their illness is a mitigating factor, which would customarily support a lesser sentence.[59] According to the Court, the risk of the death penalty is augmented for these individuals because they are more likely to offer false confessions, may not be able to aid their counsel effectively, make weak witnesses, and their demeanor often gives the impression of lack of remorse for their crimes.[60] Additionally, the Court stated that presenting mental retardation as a mitigating factor may be detrimental to their case because of the propensity for the jury to view their mental limitations as an aggravating factor due to the perceived potential for "future dangerousness."[61] Lastly, under the second prong of the "evolving standards of decency" test, the Court offered its own independent evaluation of whether the death penalty is an appropriate punishment for this population.[62] The Court stated its evaluation "reveal[ed] no reason to disagree with the judgment of the legislatures" addressing the issue and concluded that the death penalty was an excessive punishment for this population.[63]

B. Roper v. Simmons[64]

In 2005, the Court, relying heavily on its rationale in *At-*

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[58] *Atkins*, 536 U.S. at 319-20. Furthermore, executing mentally retarded defendants will not deter those who are not mentally retarded because they will continue to confront the possibility of the death penalty as a punishment. *Id.*

[59] *Id.* at 320-21.

[60] *Id.*

[61] *Id.* at 321 (citing Penry v. Lynaugh, 492 U.S. 302, 323-25 (1989)).

[62] *Id.* at 312, 321 (quoting Coker v. Georgia, 433 U.S. 584, 597 (1977)).

[63] *Id.* at 321.

[64] 543 U.S. 551 (2005).

kins, held that the Eighth Amendment barred the execution of juveniles under the age of eighteen as "cruel and unusual punishment."[65] Applying the first prong of the "evolving standards of decency" test, the Court found that the "objective indicia of consensus" provided that juveniles were "categorically less culpable than the average criminal."[66] The court arrived at this conclusion because 1) the majority of states had eliminated the death penalty as a possible sentence for juveniles, 2) the death penalty was infrequently imposed upon juveniles in states that did allow it, and 3) there was a consistent trend toward eradicating juvenile executions.[67]

The Court identified two important reasons for categorically excluding juveniles from the death penalty. First, the Court found that the penological goals of retribution and deterrence could not be achieved by executing juveniles under the age of eighteen.[68] According to the court, juveniles have diminished culpability as a result of their "immaturity and irresponsibility," their vulnerability and susceptibility to harmful influences and external pressures, and their transient personality traits.[69] The Court found that there was little evidence that the death penalty actually deterred juveniles from committing crimes;[70] however, if juveniles could be deterred, a life sentence without the possibility of parole should have a substantial deterrent effect.[71] Second, the Court was concerned that the brutality and depravity of the crime, presented by the prosecution as aggravating factors, would suppress the juvenile's ability to successfully ar-

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[65] *Id.* at 578. In order to do so, the Court had to reevaluate its earlier opinion in *Stanford v. Kentucky*. *See* Stanford v. Kentucky, 492 U.S. 361, 380 (1989) (holding the Constitution did not bar the imposition of the death penalty for juveniles between the ages of sixteen and seventeen).

[66] *Roper*, 543 U.S. at 567 (quoting *Atkins*, 536 U.S. at 316).

[67] *Id.* at 568.

[68] *Id.* at 571. The Court reiterated that the death penalty should be reserved for offenders who "commit a 'narrow category of the most serious crimes' and whose extreme culpability makes them 'the most deserving of execution.'" *Id.* at 553 (quoting *Atkins*, 536 U.S. at 319).

[69] *Roper*, 543 U.S. at 569-70.

[70] *Id.* at 571.

[71] *Id.* at 572.

gue youth as a mitigating factor.[72] Lastly, under the second prong of the "evolving standards of decency" test, the Court's own independent judgment confirmed that the execution of juveniles under the age of eighteen was forbidden by the Eighth Amendment.[73] In support of its conclusion, the Court noted that international consensus was against the death penalty for juveniles.[74]

III. MENTAL RETARDATION AND SCHIZOPHRENIA

The mental limitations of those with schizophrenia are similar to, or worse than, the mental limitations of those who are mentally retarded; therefore, those who suffer from schizophrenia at the time of offense should be precluded from society's ultimate sanction of death. This comment is not meant to advocate the innocence of schizophrenic offenders; rather it is intended to advocate the abrogation of the death penalty for those with schizophrenia because "death is different."[75] The aim of this comment is to analogize schizophrenic offenders to mentally retarded offenders in an effort to further the argument that this population should be excluded from the imposition of the death penalty. This will be achieved by analyzing the diagnosis, etiology, symptomatology, and treatment of mental retardation and schizophrenia.

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[72] *Id.* at 573.

[73] *Id.* at 563, 568-79.

[74] *Id.* at 575-76.

[75] Gregg v. Georgia, 428 U.S. 153, 188 (1976) (discussing Furman v. Georgia, 408 U.S. 238 (1972)). *See, e.g.*, Thompson v. Oklahoma, 487 U.S. 815, 838 (1988) (banning death penalty for offenders under age of sixteen at the time of the crime); Ford v. Wainwright, 477 U.S. 399, 410-11 (1986) (requiring judicial evaluation of an offender's claim of insanity prior to execution); Enmund v. Florida, 458 U.S. 782, 801 (1982) (prohibiting execution for felony murder absent a showing that the offender had culpable state of mind); Godfrey v. Georgia, 446 U.S. 420, 433 (1980) (holding execution was not appropriate for "ordinary" murder); Coker v. Georgia, 433 U.S. 584, 592 (1977) (banning death penalty for rape of an adult woman); Woodson v. North Carolina, 428 U.S. 280, 838 (1976) (prohibiting execution as a mandatory penalty for any crime); Lockett v. Ohio, 438 U.S. 586, 608-09 (1978) (requiring jury to consider mitigating circumstances); Furman v. Georgia, 408 U.S. 238, 240 (1972) (prohibiting unbridled discretion being given to jurors in sentencing).

A. Mental Retardation

1. Diagnosis

In *Atkins*, the Court did not define mental retardation, rather it left "to the State[s] the task of developing appropriate ways to enforce the constitutional restriction upon [their] execution of sentences;"[76] therefore, it is important to appropriately define the illness. The Diagnostic and Statistical Manual of Mental Disorders defines mental retardation as "subaverage general intellectual functioning" accompanied by substantial impairments in adaptive functioning in areas such as communication, self-care, social skills, work, academics, leisure, and health.[77] To be diagnosed with mental retardation, onset must occur before the age of eighteen.[78]

Generally, individuals with mental retardation present with impairments in adaptive functioning, rather than subaverage intellectual functioning.[79] Subaverage intellectual functioning is routinely defined as a score of less than seventy on an intelligent quotient (IQ) test; whereas, adaptive functioning refers to one's ability to adapt to the requirements of daily living and the expectations of his or her age and cultural group.[80] Educational and work experiences, personality traits, and other medical conditions, along with numerous other factors, may affect adaptive functioning.[81] Examining an individual's educational, social, developmental, and medical history is often helpful in assessing adaptive functioning.[82]

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[76] Atkins v. Virginia, 536 U.S. 304, 317 (2002) (quoting Ford v. Wainwright, 477 U.S. 399, 405, 416-17 (1986)).

[77] AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 41 (4th ed. Text Rev. 2000). To be diagnosed with mental retardation, an individual must have subaverage intellectual functioning and exhibit impairments in at least two areas of adaptive functioning. *Id.*

[78] *Id.*

[79] *Id.* at 42.

[80] *Id.* at 41-42.

[81] *Id.* at 42. Several scales are used to measure adaptive functioning, such as the American Association on Mental Retardation Adaptive Behavior Scale and the Vineland Adaptive Behavior Scale; reliability of scores on these scales varies significantly. *Id.*

[82] *Id.*

2. Etiology

The etiology of mental retardation may be "primarily biological or primarily psychosocial, or some combination of both."[83] In approximately thirty to forty percent of persons with mental retardation who are seen in clinical settings, the etiology cannot be determined; however, five predisposing factors have been identified: 1) heredity, 2) prenatal alterations in embryonic development, 3) problems during pregnancy or during the birth process, 4) medical conditions acquired during infancy or early childhood, and 5) environmental influences and other mental disorders.[84]

3. Symptomatology

The degree of severity of mental retardation is identified by the client's IQ level.[85] Four levels have been delineated: 1) mild mental retardation (IQ level of 50-70), 2) moderate mental retardation (IQ level of 35-49), 3) severe mental retardation (IQ level of 20-34), and 4) profound mental retardation (IQ below 20).[86] No unique personality and behavioral characteristics specifically distinguish the levels of mental retardation; however, some mentally retarded individuals exhibit "aggressive and impulsive" behaviors while others are more "passive, placid, and dependent."[87] The lower the IQ level of the individual with mental retardation, the less able he or she is to function independently.[88] Individuals who suffer from mental retardation are capable of academic skills at grade school level and below, depending on the severity of their illness.[89] Also, depending on the severity of the illness, these individuals have difficulty developing social skills and interacting with others.[90] Those indi-

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[83] *Id.* at 45.

[84] *Id.* at 45-46.

[85] *Id.* at 42.

[86] MARY C. TOWNSEND, ESSENTIALS OF PSYCHIATRIC MENTAL HEALTH NURSING 527 (4th ed. 2008).

[87] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 44.

[88] TOWNSEND, *supra* note 86, at 527.

[89] *Id.*

[90] *Id.*

viduals with severe and profound mental retardation have poor psychomotor development.[91]

4. Treatment

There is no cure for mental retardation. The symptoms of mental retardation are managed by academic, vocational, and social skills training, and behavior modification techniques are often utilized.[92] Family therapy and individual therapy is often required. Mental health treatment for mental retardation is most often performed on an outpatient basis.[93]

B. Schizophrenia

1. Diagnosis

Acute disturbances in cognition and emotion characterize schizophrenia.[94] These include acute disturbances in an individual's thought processes, language, perception, affect, and sense of self, which invariably result in severe deterioration of social and occupational functioning.[95] Generally, schizophrenia first appears in men in their late teens or early twenties and in women during their twenties or early thirties.[96] The development of schizophrenia can be viewed in four phases. Phase I characterizes the individual as being of *schizoid personality*.[97]

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[91] *Id.*

[92] *Id.* at 528.

[93] *See* Penn State Children's Hospital, Mental Retardation, http://www.hmc.psu.edu/childrens/healthinfo/m/mentalretardation.htm (last visited Mar. 5, 2009).

[94] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 298-311.

[95] *Id.* at 299.

[96] *Id.* at 307-08. The incidence of schizophrenia is slightly higher in men than in women. *Id.* *See, e.g.*, National Institute of Mental Health, Schizophrenia, http://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml (last visited Mar. 5, 2009).

[97] TOWNSEND, *supra* note 86, at 306. Individuals with schizoid personality are often described as exhibiting an indifferent attitude towards social relationships and having very restricted emotional expressions. *Id.* These individuals come across as "loners" and appear to be "cold and aloof." *Id.*

Phase II is the prodromal phase.[98] Schizophrenia is the third and active phase of the disorder, where psychotic symptoms are prominent.[99] According to the Diagnostic and Statistic Manual of Mental Disorders, a diagnosis of active schizophrenia requires that two or more of the following symptoms be present for the duration of at least one month: 1) delusions,[100] 2) hallucinations,[101] 3) disorganized speech, 4) grossly disorganized or catatonic behavior, and 5) negative symptoms.[102] In addition to finding that an individual is experiencing two of the aforementioned symptoms, diagnosis requires that since the onset of the disturbance, the individual has demonstrated a markedly lower level of functioning in one or more of the following areas: occupational abilities, interpersonal relations, or self-care.[103] Lastly, Phase IV is the residual phase, which regularly follows the active phase.[104] Many individuals with schizophrenia experience peri-

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[98] *Id.* In this stage, the individual demonstrates social withdrawal, impulse impairment and erratic behavior, neglect of personal hygiene, blunted (flat) affect, communication difficulties, bizarre ideas, and a lack of initiative. *Id.*

[99] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 302.

[100] Delusion is defined as "[a] false belief brought about without appropriate external stimulation and inconsistent with the individual's own knowledge and experience." TABER'S CYCLOPEDIC MEDICAL DICTIONARY 528 (Donald Venes et al. eds., 2001).

[101] Hallucination is defined as "[a] false perception having no relation to reality and not accounted for by any exterior stimulus; a dreamlike (or nightmarish) perception occurring while awake." *Id.* at 881. Hallucinations may affect any of the five senses. *Id.*

[102] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 312. Note that symptoms of schizophrenia are often divided into positive and negative symptoms. *Id.* The first four symptoms above are characterized as positive symptoms. *Id.* Positive symptoms are said to demonstrate "excess or distortion" of normal functioning; whereas negative symptoms are said to demonstrate a reduction or loss of normal functioning. Schizophrenia Symptoms, http://www.schizophrenia.com/diag.php (last visited Mar. 5, 2009). Examples of negative symptoms include flat affect or alogia. AM. PSYCHIATRIC ASS'N, *supra* note 77, at 312. Flat affect is defined as "virtual absence of emotional response to a situation or condition." TABER'S, *supra* note 100, at 51. Alogia is the "inability to speak." *Id.* at 75.

[103] AM. PSYCHIATRIC ASS'N, *supra* note 77 at 312. Furthermore, continuous indications of the disorder must be persistent for at least six months; this six month period must include one month of active phase symptoms and may also include symptoms characteristic in the prodromal and residual phases of the disorder. *Id.* Additionally, schizoaffective and mood disorders with psychotic features, as well as physiological effects of a general medical condition or substance abuse, must be discounted as a possible cause of the symptoms. *Id.* at 312-13.

[104] TOWNSEND, *supra* note 86, at 306. Symptoms during the residual phase are comparable to those of the prodromal phase; a flat affect and limitations in role function are

ods of remission and exacerbation, while others "remain chronically ill."[105] Rarely does a patient with schizophrenia return to pre-diagnosis functioning.[106]

2. Etiology

While the exact etiology of schizophrenia is unknown, a variable combination of factors such as psychosocial stress, genetic predisposition, biochemical dysfunction, and physiological factors are thought to contribute to its development.[107] Early theories of schizophrenia focused on psychosocial stress and family relationship factors as major influences in the development of schizophrenia;[108] however, researchers are now focusing their studies more in terms of schizophrenia as a brain disorder.[109] Nonetheless, some studies have found a positive correlation between stressful life events and schizophrenia.[110]

There is a growing body of evidence tending to show genetic vulnerability to schizophrenia.[111] However, no single gene or group of genes has been identified.[112] Individuals who have a close relative with schizophrenia are at approximately ten times greater risk of developing schizophrenia than members of the general population.[113] The theory that individuals have a ge-

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prominent. *Id.*

[105] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 308-09.

[106] *Id.* at 309.

[107] TOWNSEND, *supra* note 86, at 307-10.

[108] This was likely due to an absence of research and evidence related to a biological connection. *Id.*

[109] *Id.* at 310.

[110] *See generally* G.W. Brown & J. Birley, *Crises and Life Changes and the Onset of Schizophrenia,* 9 J. OF HEALTH & SOC. BEHAV., 203, 203-14 (1968) (finding stressful events were most likely to have occurred in the three-week period prior to the onset of symptoms). *See also* M.J. Goldstein, *Psychosocial Stress,* 13 SCHIZOPHRENIA BULL., 157 (1987).

[111] *See* Nick Craddock et al., *The Genetics of Schizophrenia and Bipolar Disorder: Dissecting Psychosis,* 42 J. OF MED. GENETICS 193, 193-204 (2005); Shusuke Numata et al., *TGFBR2 Gene Expression and Genetic Association with Schizophrenia,* 42 J. OF PSYCHIATRIC RES. 425, 425-32 (2008); Anita Thapar et al. *The Contribution of Gene-Environment Interaction to Psychopathology,* 19 DEV. & PSYCHOPATHOLOGY, 989, 989-1004 (2007).

[112] *On the Trail of Schizophrenia,* HARV. MENTAL HEALTH LETTER, Mar. 2005, at 2.

[113] *The Causes of Schizophrenia,* http://www.schizophrenia.com/research/surg.general.2002.htm (last visited Mar. 5,

netic predisposition towards schizophrenia is espoused by the fact that an identical twin of an individual with schizophrenia has a greater risk of developing the disease than a sibling or fraternal twin (non-identical).[114] Furthermore, "identical twins reared apart have the same rate of development of schizophrenia as do those reared together,"[115] and unlike biological relatives, adoptive relatives do not have an increased risk of development of the disease.[116]

The oldest and most researched etiology theory of schizophrenia ascribes a pathogenic role to atypical brain biochemistry.[117] Studies suggest that manifestations of acute schizophrenia may be related to increased numbers of dopamine receptors in the brain.[118] Pharmacological support for this theory exists: Amphetamines, which increase levels of dopamine, induce psychotic symptoms,[119] while neuroleptics lower brain levels of dopamine by blocking dopamine receptors, [120] thus reducing the schizophrenic symptoms.[121] Numerous other biochemicals have

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2009).

[114] *Id.* "The rate of schizophrenia among monozygotic (identical) twins is four times that of dizygotic (fraternal) twins and approximately 50 times that of the general population." TOWNSEND, *supra* note 85, at 307.

[115] TOWNSEND, *supra* note 85, at 307. However, in approximately forty-fifty percent of cases studied involving twins, only one of a pair of monozygotic twins developed the disorder; this suggests that environmental factors may interact with genetic factors. *Id.*

[116] *The Causes of Schizophrenia*, http://www.schizophrenia.com/research/surg.general.2002.htm (last visited Mar. 5, 2009).

[117] TOWNSEND, *supra* note 86, at 307. As early as the mid-19th Century, theorists explained schizophrenia as a "chemical disturbance." *Id.*

[118] *See generally* E.M. Meisenzahl et al., *The Role of Dopamine for the Pathophysiology of Schizophrenia,* 19 INT'L REV. OF PSYCHIATRY 337 (Aug. 2007); Noboru Sakumoto et al., *Dopamine D₂ Receptor Gene Polymorphisms Predict Well the Response to Dopamine Antagonists at Therapeutic Dosages in Patients with Schizophrenia,* PSYCHIATRY & CLINICAL NEUROSCIENCES, Apr. 2007, at 174-75; TOWNSEND, *supra* note 86, at 309.

[119] Sunday Aderemi Adeyemo, *Can the Action of Amphetamine on Dopamine Cause Schizophrenia?*, 39 PSYCHOL. & EDUC.: AN INTERDISC. J., 29, 29-39 (2002). *See also* John B. Murray, *Psychophysiological Aspects of Amphetamine-Methamphetamine Abuse*, 132 J. OF PSYCHOL. 227, 234-35 (1998).

[120] These are often referred to as anti-psychotic drugs. TABER'S, *supra* note 100, at 1456. Common anti-psychotics are Haldol, Thorazine, and Clozapine. *Id.*

[121] TOWNSEND, *supra* note 86, at 309.

also been linked to the predisposition to schizophrenia. For example, irregularities in the neurotransmitters norepinephrine, serotonin, acetylcholine, and gamma-aminobutyric acid (GABA) as well as in neuroregulators such as prostaglandins and endorphins have been identified.[122]

a. Recent Advances

As a result of recent advances in diagnostic imaging that allow researchers to detect brain abnormalities in schizophrenic patients, researchers are now focusing their efforts in terms of schizophrenia as a disease of the brain. These diagnostic techniques include: 1) computerized EEG mapping, 2) computerized tomographic (CT) scans, 3) magnetic resonance imaging (MRI), 4) positron emission tomography (PET) scans, and 5) single photon emission computed tomography (SPECT).[123] Computerized EEG mapping assesses electrical activity in the brain; it is utilized to denote statistical relationships between schizophrenics and control groups.[124] CT scans are utilized to detect lesions, abscesses, areas of infarction, and aneurysms by measuring the dimensions of brain structures.[125] MRI detects "brain edema, ischemia, infection, neoplasm, trauma," and other changes in the brain by assessing the anatomical and biochemical changes in the brain.[126] PET measures particular areas of brain performance, such as "glucose metabolism, oxygen utilization, blood flow," and, of particular interest, "neurotransmitter/receptor interaction."[127] SPECT is similar to PET and is used to visualize brain activity.[128] The newer techniques such as PET, SPECT, and functional magnetic resonance imaging (fMRI) allow re-

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[122] *Id.*

[123] *Id.* at 45. Garry D. Honey & Edward T. Bullmore, *Functional Neuroimaging and Schizophrenia*, 1 PSYCHIATRY 26, 26-29 (2002).

[124] TOWNSEND, *supra* note 86, at 46.

[125] *Id.* CT scan abnormalities are present in approximately forty percent of schizophrenic patients. *Id.*

[126] *Id.* at 46.

[127] *Id.*

[128] *Id.*

searchers to determine localized regional brain activity.[129]

A number of physical abnormalities in the brain of schizophrenic patients have been revealed as a result of these studies.[130] Common anatomical abnormalities identified in the schizophrenic brain include lateral ventricular enlargement, enlargement of the sulci or fissures on the cerebral surface, atrophy of the cerebellum, and decreased temporal lobe size.[131] Studies have reported gray matter loss in the schizophrenic brain of up to twenty-five percent in some areas.[132] This loss of gray matter is reported to be progressive and attributable to the disease process and antipsychotic medications.[133] Together, these abnormalities may represent brain atrophy.[134] Studies of the schizophrenic brain are now moving away from examining isolated regions of the brain toward functional imaging to examine "neural circuits" and biochemical activity in the brain.[135]

3. Symptomatology

The Diagnostic and Statistic Manual for Mental Disorders recognizes five forms of schizophrenia.[136] The five forms are as follows: 1) disorganized schizophrenia, 2) catatonic schizophrenia, 3) paranoid schizophrenia, 4) undifferentiated schizophrenia, and 5) residual schizophrenia.[137] Although characteristics differ among the forms, the most common symptoms exhibited by schizophrenics include: primitive, disorganized, or catatonic

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[129] Honey, *supra* note 123, at 26.

[130] TOWNSEND, *supra* note 86, at 309.

[131] *Id.*; Christian Gaser et al., *Ventricular Enlargement in Schizophrenia Related to Volume Reduction of the Thalamus, Striatum, and Superior Temporal Cortex*, 161 AM. J. PSYCHIATRY 154, 154-56 (2004).

[132] *Schizophrenia is a Disorder of the Brain*, http://www.schizophrenia.com/disease.htm#significant (last visited Mar. 5, 2009).

[133] *See supra* note 4 and accompanying text.

[134] Gaser, *supra* note 131, at 154-56.

[135] Honey, *supra* note 123, at 26. PET and SPECT enable researchers to assess the level of dopamine (and other biochemical) receptor availability in schizophrenia. *Id.*

[136] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 303. It also identifies various other psychotic disorders including schizoaffective disorder, brief psychotic disorder, schizophreniform disorder, delusional disorder, shared psychotic disorder, psychotic disorder due to a general medical condition, and substance-induced psychotic disorder. *Id.* at 317-43.

[137] *Id.* at 303.

behavior; flat affect; bizarre mannerisms; incoherent communication; neglected personal hygiene; and extreme social impairment.[138] For example, individuals suffering from schizophrenia often hear voices speaking to them that others cannot hear, they think that others are "broadcasting their thoughts to the world," and they often believe that others are conspiring to hurt them.[139]

4. Treatment and Implications

A cure for schizophrenia does not exist.[140] The symptoms of schizophrenia, however, can be controlled to an extent by pharmacotherapy and psychosocial intervention/counseling in the areas of living skills, social skills, rehabilitation, and family therapy.[141] While pharmacotherapy is important to controlling the symptoms of schizophrenia, schizophrenics often do not follow through with their prescribed medication or treatment regimen due to lack of awareness or "insight" caused by impairment in brain function.[142] Schizophrenics frequently discontinue their medications because of 1) the harsh side effects of the medications, 2) barriers to obtaining the medication such as costs, and 3) thought processes that cause the individual to forget to take their medications.[143] The refusal or incapacity to

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[138] TOWNSEND, *supra* note 86, at 317. "Paranoid schizophrenia is characterized mainly by the presence of delusions of persecution or grandeur and auditory hallucinations related to a single theme." *Id.* at 311. These individuals are "often tense, suspicious, and guarded and may be argumentative, hostile, and aggressive." *Id. See also* AM. PSYCHIATRIC ASS'N, *supra* note 77, at 313-14.

[139] Nat'l Inst. of Mental Health, *What is Schizophrenia?*, http://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml (last visited Mar. 5, 2009).

[140] *Id.*

[141] TOWNSEND, *supra* note 86, at 318-27. Schizophrenia may be treated on an inpatient or outpatient basis. *Id.*

[142] Celso Arango et al., *Relationship of Awareness of Dyskinesia in Schizophrenia to Insight into Mental Illness*, 156 AM. J. PSYCHIATRY 1097, 1097 (July 1999). Lack of insight prevents the individual from being able to comprehend that he or she is sick; therefore, when he or she experiences psychotic symptoms, such as delusions or hallucinations, he or she thinks they are based in reality. *Id.* Because these individuals do not think they are sick, they frequently refuse to take their medication. *Id. See also* Lorenzo Pia & Marco Tamietto, *Unawareness in Schizophrenia: Neuropsychological and Neuroanatomical Findings,* 60 PSYCHIATRY & CLINICAL NEUROSCIENCES 531, 531-32 (2006).

[143] Diana O. Perkins, *Predictors of Noncompliance in Patients with Schizophrenia*, 63

comply with their prescribed treatment regimen often produces an exacerbation of psychotic symptoms which can lead to hospitalization, suicide attempts, homelessness, incarceration, or violent behavior.[144]

Schizophrenia produces lengthy hospitalizations, chaos in family life, and exorbitant costs to individuals and governments, as well as social stigma. According to the National Institute of Mental Health, approximately 1.1 percent of the population age eighteen and older has schizophrenia,[145] and schizophrenia ranks ninth among the leading causes of disability worldwide.[146] Schizophrenia accounts for twenty-five percent of all mental health costs, and it makes up thirty percent of all inpatient mental health admissions.[147] Only twenty-eight percent of individuals suffering from schizophrenia live independently, while the remaining seventy-two percent require some kind of assistance.[148] Furthermore, schizophrenia is strongly associated with suicide/self-harm, victimization, violence, substance abuse, homelessness, and unemployment.[149]

J. CLINICAL PSYCHIATRY 1121, 1123 (2002); Jaya Pinikahana et al., *Exploring the Complexity of Compliance in Schizophrenia*, 23 ISSUES IN MENTAL HEALTH NURSING 513, 513-14 (2002).

[144] Treatment Advocacy Center, *Why Individuals with Severe Psychiatric Disorders Often Do Not Take Their Medications*, http://www.psychlaws.org/BriefingPapers/documents/pdfBPWhyindividualsdonottakemedications.pdf.

[145] Nat'l Inst. of Mental Health, *The Numbers Count: Mental Disorders in America*, http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-america.shtml#Schizophrenial; Schizophrenia Facts and Statistics, http://www.schizophrenia.com/szfacts.htm (last visited Mar. 5, 2009).

[146] World Health Organization, *An Overview of a Strategy to Improve the Mental Health of Underserved Populations*, http://www.who.int/mental_health/media/en/46.pdf (last visited Mar. 26, 2009).

[147] Schizophrenia Facts and Statistics. http://www.schizophrenia.com/szfacts.htm (last visited Mar. 26, 2009).

[148] Six percent of these individuals live in shelters or are homeless, six percent live in jails or prisons, ten percent live in nursing homes, twenty-five percent live with a family member, and twenty percent live in supervised housing (group homes, etc.). E. FULLER TORREY, SURVIVING SCHIZOPHRENIA: A MANUAL FOR FAMILIES, PATIENTS, AND PROVIDERS 38 (5th ed. 2006).

[149] Iain Kooyman et al., *Outcomes of Public Concern in Schizophrenia*, 191 BRIT. J. OF PSYCHIATRY 29, 29-36 (2007). Individuals suffering from schizophrenia often suffer from victimization. Paul B. Fitzgerald et al., *Victimization of Patients with Schizophrenia and*

The public often views individuals suffering from schizophrenia negatively.[150] Perceived dangerousness underlies this stigmatization of schizophrenics.[151] While studies have shown that people with severe mental illness tend to be more violent than those without severe mental illness, the public's fear of these individuals seems to be out of proportion because other risk factors contribute to the violence such as age, gender, educational level, and violent history.[152] Additionally, the public's view of these individuals is heavily influenced by the negative portrayal of those with schizophrenia in mass media.[153] One study has shown that when the public is educated about the illness or has contact with a schizophrenic individual, they perceive schizophrenics as less dangerous than those who are unaware of the disorder and who have not had contact with a schizophrenic individual.[154] This suggests that education is key to reducing stigmatizations toward individuals with schizophrenia.

IV. Comparing Schizophrenia to Mental Retardation

Because the Supreme Court's holding in *Atkins* does not extend to individuals with schizophrenia, it is important to compare and contrast the disorders. Neither mental retardation nor schizophrenia is within an affected individual's volition; affected individuals have no control over their illness. Both mental retardation and schizophrenia are considered to be the result of multi-dimensional factors and both involve impairments in cognitive and emotional capabilities. While schizophrenia tends to occur in one's twenties or thirties, rather than before the age of eighteen, the cognitive and emotional impairments experienced are analogous to the adaptive behavior deficits experienced by individuals with mental retardation. Individuals suffering from

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Related Disorders, 39 Australian & New Zealand J. of Psychiatry 169, 169-74 (2005).

[150] David L. Penn et al., *Dispelling the Stigma of Schizophrenia: II. The Impact of Information on Dangerousness*, 25 Schizophrenia Bull., 437, 437-46 (1999).

[151] *Id.* at 437-38.

[152] *Id.* at 438.

[153] *Id.*

[154] *Id.*

schizophrenia, like individuals with mental retardation, display social and occupational dysfunction, such as an inability to hold down employment, impaired social relationships, social isolation, law violations, familial stress, and drug abuse.[155] These impairments can be incapacitating. Individuals with mental retardation and individuals with schizophrenia both have problems communicating, controlling impulses, thinking coherently, processing information, and behaving appropriately.

Although individuals suffering from schizophrenia might not be of subaverage intelligence as are individuals with mental retardation, the acute psychotic symptoms experienced by these individuals distort their perceptions of reality. An individual experiencing hallucinations and delusions often hears voices speaking to him and often thinks others are conspiring against him.[156] These impairments are very frustrating due to their acute nature. Although schizophrenia, unlike mental retardation, does not consistently present itself, once an individual experiences an acute episode, rarely does he or she return to premorbid functioning.[157]

Social stigma often attaches to individuals with schizophrenia and mental retardation; however, schizophrenics probably tend to be more feared than individuals with mental retardation. This is most likely attributed to the fact that schizophrenia does not present until later in life, often after the individual has lived a relatively normal life, and to the negative portrayal of schizophrenia in the media. Furthermore, until recently there was no real explanation for the disease. However, the recent advances in diagnostic imaging, allowing researchers to perceive the abnormalities of the schizophrenic brain, confirm that these individuals cannot control their bizarre mannerisms and behavior.

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[155] *Id.*; Office of the Surgeon General, *Mental Health: A Report of the Surgeon General*, http://www.surgeongeneral.gov/library/mentalhealth/chapter2/conc2.html#mental (last visited Mar. 5, 2009).

[156] *See supra* note 139 and accompanying text. For example, an individual may think the TV is talking to him or her or that God is instructing him or her to commit a certain act. *Id.*

[157] *Id.*

V. SCHIZOPHRENIC OFFENDERS SHOULD BE EXCLUDED FROM THE IMPOSITION OF THE DEATH PENALTY

A. Evolving Standards of Decency

1. Prong One: Objective Factors

Currently, there is little state legislation that protects schizophrenic patients from the death penalty, unlike the legislation discussed in *Atkins* and *Roper*;[158] however, there is evidence that the public's standards of decency are evolving and plausible arguments exist for expanding the holding of *Atkins* to those who suffer from schizophrenia. For example, national polls suggest that the United States public is opposed to the death penalty for the "mentally ill."[159] In a Gallup poll conducted in May of 2002, approximately seventy-five percent of Americans responded that they opposed the death penalty when asked whether they favored or opposed it for the "mentally ill."[160] Furthermore, almost every state considers mental illness a mitigating factor to consider in the sentencing phase of capital trials.[161]

Like the general consensus among professional organizations in *Atkins* that the death penalty should be barred for mentally retarded offenders, there is a general consensus among professional organizations such as the American Psychological Association, the American Psychiatric Association, and the American Bar Association, that the death penalty should be barred for schizophrenic offenders.[162] One year after *Atkins* was decided, the American Bar Association (ABA) established a task force to consider whether the particular concerns underlying *At-*

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[158] *See supra* note 5 and accompanying text.

[159] Gallup Poll, *Death Penalty*, http://www.pollingreport.com/crime.htm.

[160] *Id.*

[161] *See* American Bar Association Section of Individual Rights and Responsibilities, *Death Without Justice: A Guide for Examining the Administration of the Death Penalty in the United States,* 63 OHIO ST. L.J. 487, 529 (2002).

[162] Ronald J. Tabak, *Mental Disability and Capital Punishment: A More Rational Approach to a Disturbing Subject*, HUMAN RIGHTS, Spring 2007, at 5.

kins applies to individuals with other types of mental illness.[163] The task force found that these same concerns do apply, and it drafted recommendations. The recommendations of the task force have since been adopted by the ABA, the American Psychological Association, and the American Psychiatric Association.[164] These organizations are of the view that offenders should not be sentenced to death if "at the time of offense" they suffer from a "severe mental disorder or disability that significantly impair[s] their capacity (a) to appreciate the nature, consequences or wrongfulness of their conduct, (b) to exercise rational judgment in relation to conduct, or (c) to conform their conduct to the requirements of the law."[165] The ABA has encouraged states that continue to recognize capital punishment for mentally ill offenders to adopt these recommendations.[166] International organizations also oppose the death penalty for the mentally ill. For example, the Office of the United Commission for Human Rights has urged all non-abolitionist countries to refrain from imposing the death penalty "on a person suffering from any form of mental disorder or to execute any such person."[167]

Executing persons with schizophrenia does not further the primary penological goals of retribution and deterrence. Like mentally retarded offenders, the diminished ability of schizophrenic offenders to "understand and process information, to learn from experience, to engage in logical reasoning, or to control impulses," is unlikely to deter them from committing crimes.[168] Because of schizophrenics' lack of impulse control and impaired thought processes, crimes they commit are unlikely to

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[163] *Id.* This task force was composed of lawyers, mental health practitioners, and academic scholars. *Id.*

[164] *Id.*

[165] ABA Section of Individual Rights and Responsibilities et al., Recommendation 122A (2006), http://www.abanet.org/media/docs/122A.pdf (last visited Mar. 5, 2009).

[166] *Id.* It is important to note that the ABA resolution, unlike *Atkins*, does not automatically exempt individuals with mental illness, even severe mental illness, from the death penalty. *See* Tabak, *supra* note 162, at 6.

[167] Commission on Human Rights Resolution 2002/77, http://www.unhchr.ch/Huridocda/Huridoca.nsf/TestFrame/e93443efabf7a6c4c1256bab00500ef6 (last visited Mar. 26, 2009).

[168] Atkins v. Virginia, 536 U.S. 304, 319-20 (2002).

be the result of premeditation and deliberation. Additionally, lack of insight prevents schizophrenics from appreciating the legal consequences of their actions; therefore, the goal of deterrence cannot be achieved through the execution of patients suffering from schizophrenia.

The cognitive and emotional impairments of schizophrenic individuals make them less morally culpable than individuals who do not suffer from the disease; therefore, because retribution requires punishment in proportion to the defendant's culpability, the penological goal of retribution is not advanced by the execution of persons with schizophrenia. Diagnostic technology is yielding objective evidence of abnormal brain functioning in individuals with schizophrenia. As a result, researchers can now objectively prove that these individuals are truly suffering from an illness: an illness over which they have no control. Diagnostic imaging has revealed changes that demonstrate atrophy, a wasting away, of the functional brain matter of individuals with schizophrenia, which objectively supports the proposition that these individuals are less culpable than others.[169]

Schizophrenic offenders, like mentally retarded offenders, are at increased risk to be disadvantaged in legal proceedings. Like mental retardation has the potential to be treated as an aggravating factor to show future dangerousness, schizophrenia also has the potential to be used as an aggravating factor to show future dangerousness.[170] Use as an aggravator has the potential to, and some studies suggests it does, overshadow the mitigating effect of the illness in the minds of jurors.[171] Schizophrenia is probably even more likely to be viewed as an aggravator than mental retardation because the onset of schizophrenia typically occurs later in life, and the disease is characterized by periods of remission. Furthermore, medications often mask the symptoms of the illness; this potential is even greater when

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[169] *See supra* notes 129-33 and accompanying text.

[170] *See supra notes* 150-52 and accompanying text.

[171] Erica Beecher-Monas & Edgar Garcia-Rill, *Genetic Predictions Of Future Dangerousness: Is There a Blueprint for Violence?*, 69 LAW & CONTEMP. PROBS. 301, 301-02 (2006).

these individuals are incarcerated because someone ensures they get their medication, which controls their symptoms. While control of symptoms is encouraged, it has the potential of leading the jury to conclude that schizophrenics are not sick. Additionally, the Court noted in *Atkins* that because of their illness, mentally retarded offenders have the potential to make poor witnesses and to ineffectively aid their defense counsel; schizophrenic offenders have the same potential.[172] For example, the schizophrenic offender's flat affect, which is exhibited by a monotonous tone of voice and diminished facial expressions, can lead jurors to believe he or she lacks remorse for his or her crime.[173] Additionally, while schizophrenics may be found competent to stand trial, because of delusions or impaired thought processes and judgment, these individuals may be suspicious of their defense counsel, refuse to cooperate, or sometimes believe that representation is unnecessary.[174] Because of the potential for schizophrenia to put the offender at a disadvantage during criminal proceedings, especially during sentencing, capital punishment should be excluded as a punishment for schizophrenic offenders.

a. Refuting the Opposition

Three conceivable arguments against extending the rationale of *Atkins* to schizophrenic offenders are: 1) schizophrenia is harder to diagnose, 2) schizophrenia is not as mitigating as mental retardation or youth, and 3) individuals with schizophrenia are more dangerous than mentally retarded offenders. However, all these arguments can be adequately rebutted.

First, some might argue that schizophrenia is harder to de-

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[172] *See supra* note 60 and accompanying text.

[173] *See supra* note 98.

[174] *See* Martin Sabelli & Stacey Leyton, *Train Wrecks and Freeway Crashes: An Argument for Fairness and Against Self Representation in the Criminal Justice System*, 91 J. CRIM. L. & CRIMINOLOGY 161, 185-86, 197-98 (2000) (raising the issue of whether assistance of counsel should be mandatory to serve the best interests of the mentally ill offender). *See also* Brief of Petitioner, Panetti v. Quarterman, 127 S. Ct. 2842 (2007) (No. 06-6407) (as a result of schizophrenic delusion, the defendant became suspicious of attorneys and waived his right to counsel).

fine than mental retardation because it demands a more subjective assessment of symptoms than does objective IQ testing; however, limited adaptive functioning is also a requirement for the diagnosis of mental retardation, and it is very subjective. Both schizophrenia and mental retardation require an individual to have limitations in adaptive functioning in order to be diagnosed: a requirement that is inherently subjective in nature. However, with the capability that now exists to demonstrate actual physiological changes in the brain of schizophrenics, this argument loses its merit. Also, opponents could argue that schizophrenic offenders might successfully feign mental illness to evade death; theoretically this is possible, however, studies have shown a high rate of reliability of diagnosis and that malingering is difficult.[175] Another contention that might be argued is that schizophrenia is a variable condition, whereas mental retardation is constant and permanent; however, although the course of schizophrenia varies among individuals, full remission rarely occurs.[176] Even if these concerns have merit, the better course of action would be to place a heavy burden of proof on the individual offender to show he was suffering from psychosis at the time the crime was committed.

Second, some may argue that schizophrenia is not as mitigating a factor as mental retardation. These individuals would argue schizophrenic offenders are more responsible for their actions because they are not developmentally impaired and have greater capacity to understand and abide by the law. Others might argue that schizophrenia is more easily treated than mental retardation. While these differences theoretically exist, once psychosis presents, it rarely dissipates.[177] For example, once delusions and hallucinations present, any understanding and capacity gained from prior experiences have little influence upon the defendant's behavior. Moreover, with recent technological advances, evidence now exists to prove that schizophrenics are

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[175] Christoper Slobogin, *What Atkins Could Mean for People With Mental Illness*, 33 N.M. L. REV. 293, 307-08 (2003) (citing MICHAEL PERLIN, THE JURISPRUDENCE OF THE INSANITY DEFENSE 238-41 (1994)).

[176] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 308-09.

[177] AM. PSYCHIATRIC ASS'N, *supra* note 77, at 309.

developmentally impaired. Similarly, failure to obtain treatment or take prescribed anti-psychotic medications cannot support the argument that schizophrenics are somehow more responsible for their behavior because many resist taking medication as a result of negative side effects or impaired thought processes.[178] Furthermore, pharmacological treatment is not always successful.[179]

Third, perceived dangerousness has been shown to be the overriding factor during the sentencing phase of the trial.[180] Studies have revealed that schizophrenics tend to be more violent than the average individual; however, in the death penalty context, the appropriate comparison is between schizophrenics and non-mentally ill offenders.[181] When compared to the latter, research has shown that individuals with mental illness are "no more, and probably less, dangerous" than non-mentally ill offenders.[182]

2. Prong Two: Persuading the Court

As previously mentioned, the Court also has to utilize its own judgment under the evolving standards of decency test.[183] This prong is frequently merged with the first prong or briefly brushed over; nonetheless, based on all the objective factors discussed above, the Court's own judgment should be influenced by these factors. Objective evidence exists to support that individuals suffering from schizophrenia should not be subjected to capital punishment; however, more legislative efforts need to be undertaken to evidence that society's evolving standards no longer support capital punishment for schizophrenics. In order

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[178] *See supra* notes 141-43 and accompanying text.

[179] *Id.*

[180] Sally Costanzo & Mark Costanzo, *Life or Death Decisions: An Analysis of Capital Jury Decision Making Under the Special Issues Sentencing Framework*, 18 LAW & HUM. BEHAV. 151 (1994). *See supra* note 172 and accompanying text.

[181] Slobogin, *supra* note 175, at 312.

[182] *Id.* (citing James Bonta et al., *The Prediction of Criminal and Violent Recidivism Among Mentally Disordered Offenders: A Meta-Analysis*, 123 PSYCHOL. BULL. 123 (1998)).

[183] *See supra* notes 14-15 and accompanying text.

to attain this goal, courts and juries, as well as the general public, need to be educated about schizophrenia. Studies supporting schizophrenia as a disorder of the brain are powerful objective evidence. The public needs to be educated about these findings in order to appreciate that the behavioral manifestations exhibited by these individuals is outside the realm of their control, just like the behavioral manifestations of the mentally retarded offender. Public education of the disease process would hopefully spur state legislatures to adopt the provisions set forth by the ABA.

VI. Conclusion

The concept of "evolving standards of decency" that was espoused in *Atkins* and *Roper* suggests a movement towards a more informed analysis, which considers the developmental, functional, and cognitive make-up of criminal offenders when assessing moral culpability. Although current state and federal legislation may not yet be at the level the Court found it to be when it decided that mentally retarded and juvenile offenders should be excluded from the imposition of death, existing views of professional organizations, public opinion, and the beliefs of international communities indicate that society's standards are evolving to reflect that the imposition of death for schizophrenic offenders is "cruel and unusual." The newfound capability of illustrating through reliable scientific imaging techniques that the schizophrenic brain is substantially impaired compared to the normal brain is the most objective evidence to date that these individuals are less morally culpable than the average offender. These advances bolster the proposition that retribution and deterrence cannot be achieved in this population. Additionally, the risk of disadvantage in the sentencing phase of trial also supports excluding individuals with schizophrenia from the imposition of death.

A conscious effort to inform the public, legislature, and players in the criminal justice system should be undertaken to encourage incorporation of the realities of schizophrenia, and other mental illness, into the decision-making processes of legislative bodies. For "[i]f the culpability of the average murderer is

insufficient to justify the most extreme sanction," surely the lesser culpability of an individual with schizophrenia, does not warrant that form of retribution.[184]

Bethany C. Bryant

[184] Atkins v. Virginia, 536 U.S. 304, 319 (2002) (citing Godfrey v. Georgia, 446 U.S. 420, 433 (1980)).

COMMENT

METADATA: High-Tech Invisible Ink Legal Considerations

"Some aspects of ESI have no counterpart in print media, metadata being the most obvious. Metadata, which most computer users never see, provide information about an electronic file . . ."[1]

I. WHAT IS METADATA?

Metadata simply defined means data about data. Metadata is a term that has become more recognized in recent years with computer technology, but it is not new. Most of us were exposed to metadata as children when we used the library catalog. Each card in the catalog was metadata because it contained "data about data." Advancements in computer technology have increased processing speeds and storage capacity, creating the need and ability to store large amounts of metadata for organizing and searching information stored in a computer.

This comment begins with a brief overview of metadata including how it is created, its advantages and disadvantages and how it can be removed. Electronic evidence, in standard forms such as word-processing documents or digital photos, has been discussed and considered in many forums. Metadata, unlike these types of electronic evidence, does not have a strong

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[1] BARBARA J. ROTHSTEIN, RONALD J. HEDGES, & ELIZABETH C. WIGGINS, MANAGING DISCOVERY OF ELECTRONIC INFORMATION: A POCKET GUIDE FOR JUDGES 3 (2007), *available at* http://www.fjc.gov/public/pdf.nsf/lookup/eldscpkt.pdf/$file/eldscpkt.pdf [hereinafter MANAGING DISCOVERY OF ELECTRONIC INFORMATION].

analogous form in a non-electronic medium. Some liken it to invisible ink. Some types of metadata could also be compared to the impressions left behind on a pad of paper from previous notes. Since it is unlike other electronic evidence and a better understanding of metadata is emerging, consideration of how this type of information will impact the legal community either in advice to clients regarding day-to-day activities or in the handling of litigation is important. Parts II and III focus on issues surrounding discovery and admissibility of metadata.

A. Metadata Associated with Various File Types

Two types of metadata, system and application, are generally associated with a file. System metadata is usually metadata that is common to all files types. Examples of system data would be the date and time a file was created and modified, the file name and the owner or author of the file. The Sedona Principles, developed by the Sedona Conference[2] Working Group on Electronic Document Retention and Production, note that system metadata is typically created by a user or organization's information management system and may not be embedded within the file, but stored in an external management information system.[3]

Application metadata, on the other hand, is created in association with software programs and is embedded and travels with the file. Some programs that people run on a daily basis are programmed to automatically save more detailed metadata. The following paragraphs discuss the types of metadata embedded with two popular word-processing programs and digital photography.

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[2] The Sedona Conference is a non-profit "research and educational institute dedicated to the advancement of law and policy in the areas of antitrust law, complex litigation and intellectual property rights." The Sedona Conference, http://www.thesedonaconference.org/content/faq (last visited May 6, 2009).

[3] WORKING GROUP SERIES, THE SEDONA CONFERENCE, THE SEDONA PRINCIPLES: BEST PRACTICES RECOMMENDATIONS & PRINCIPLES FOR ADDRESSING ELECTRONIC DOCUMENT PRODUCTION 60 (2007) [hereinafter THE SEDONA PRINCIPLES].

1. Microsoft Word

Microsoft Word, which is notorious for saving large quantities of metadata, retains the following categories of metadata:[4]

- Track Changes: Shows changes that have been made including text that has been deleted.
- Comments: Allows people viewing a document to make comments that do not become part of the text.
- Versions: Displays different versions of the same document.
- Template: Reveals information about the origins of the document.
- Last 10 Authors: Provides last 10 people to have worked on a document.
- Document Statistics: Lists people who worked on document, how long they worked on it and how many revisions they made.
- Routing Slip: Reveals the names of people who have received copies of the document.

This list may look daunting, but it is important to note that some of this information can be eliminated if the track changes feature is turned off or template and version information is cleared from the document.[5] Microsoft's website notes that the last ten authors is one set of metadata that cannot be prevented in Word documents.[6] If this is an issue, Microsoft recommends saving the document in Rich Text Format (RTF) or as a PDF.[7]

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[4] Jason Krause, *Hidden Agendas: Unlocking Invisible Electronic Codes can Reveal Deleted Text, Revisions*, 90 A.B.A. J. 26, 27 (2004).

[5] How to Minimize Metadata in Microsoft Word 2000 Documents, http://support.microsoft.com/default.aspx?scid=kb;EN-US;237361 (last visited Apr. 24, 2009). Please note the information referenced is for Microsoft Word 2000, but information on later versions is also available online.

[6] *Id.*

[7] *Id.* A PDF file is a format created by Adobe systems which enables documents to be "viewed and printed as they were intended in their original application by practically any computer" THE SEDONA CONFERENCE GLOSSARY: E-DISCOVERY & DIGITAL INFORMATION MANAGEMENT 39 (Conor R. Crowley & Sherry B. Harris eds., 2d ed. 2007) [hereinafter SEDONA CONFERENCE GLOSSARY].

2. WordPerfect

Although Microsoft Word has received some notoriety; it is not the only word-processing software that retains metadata. Here are some examples of metadata stored in WordPerfect documents.[8]

- Comments and hidden text
- Styles
- Undo/Redo history
- Your username, initials, and company or organization name
- Document summary information
- Document revision annotations
- Header and footer information
- Hyperlinks
- Non-visible portions of object linking and embedding (OLE) objects

3. Digital Photographs

Digital photographs also store a wealth of information. Exchange Information File Format (EXIF) is the customary metadata embedded in images by most digital cameras. Unlike some metadata in word-processing programs, digital photo EXIF information is readily accessible in Windows Explorer.[9] The information can be found in the Properties dialog box under Advanced Summary. The Advanced Summary breaks the information down into three categories:

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[8] COREL CORPORATION, MINIMIZING METADATA IN WORDPERFECT 12 DOCUMENTS 4 (2004), http://www.corel.com/content/pdf/wpo12/Minimizing_Metadata_In_WordPerfect12.pdf.

[9] EXIF data may be altered or removed by software programs, but should be accessible in unedited photos. *See generally*, Daniel Engber, *Are the Duke Lacrosse Photos Legit? Can the time stamp on a digital photo be altered?*, SLATE, Apr. 20, 2006, http://www.slate.com/id/2140303/.

Category	Information Provided*			
Image	Width Height Horizontal Resolution Vertical Resolution Bit Depth	Frame Count Equipment Make Camera Model Creation Software Color Representation	Flash Mode Focal Length F-Number Exposure Time ISO Speed Light Source	Metering Mode Exposure Program Exposure Compensation Date Picture Taken
Description	Title	Subject	Keywords	Comments
Origin	Author			

* This list may not be inclusive for all cameras.

Windows Explorer allows users to edit the information in the Description and Origin Categories. The amount of information embedded in each digital photo varies depending on the type of camera or method used to create the photo. More sophisticated cameras tend to embed more data in their files. Digitizing photos through scanning eliminates all the data the camera would normally embed.

More advanced metadata protocols have been developed by the International Press Telecommunications Council (IPTC)[10] and Adobe Systems (Extensible Metadata Platform (XMP)).[11] These protocols allow users to add more metadata to a photo beyond the EXIF information embedded by digital cameras.

B. How is Metadata Created?

Two general types of metadata exist, computer-stored records and computer-generated records.[12] Computer-stored

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[10] *See infra* notes 13-18 and accompanying text.

[11] SALLY WIENER GROTTA, PC MAGAZINE GUIDE TO DIGITAL PHOTOGRAPHY 105-06 (2004).

[12] The terms computer-stored and computer-generated have been used to categorize

records are created by a user for instance when the description or origin category for a digital photo is altered and then stored on the computer. Computer-generated records are automatically created by a program and then stored on the computer. In digital photography, digital cameras create computer-generated metadata by automatically 'stamping' a photo with information regarding the camera, camera settings and time of photo.

C. The Pros and Cons of Metadata

1. The Pros

Typically, metadata is a useful tool. Website programmers use it to organize large amounts of information and make it easy and efficient to retrieve. Word-processing programs use the information to help retrieve lost data and track changes.

The International Press Telecommunications Council (IPTC) offers an example of how metadata can be helpful.[13] In 1990, the IPTC developed its Information Interchange Model (IIM) standard, which Adobe Photoshop later adopted.[14] Additional needs were identified from the photo workflow process and different users at each step.[15] In response, the IPTC Core Schema for XMP was adopted to resolve ambiguities, and later the IPTC issued a White Paper on Photo Metadata to address metadata and process standards for their industry.[16] Specifically, the IPTC White Paper provides "a list of metadata properties which are believed to be highly required and helpful . . . [which] the IPTC will consider . . . a set of business requirements for the development of the next version of the

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all electronic documents. Howard L. Nations & Cindy L. Nations, ALI-ABA Continuing Legal Education: The Rules of Digital Evidence (2007).

[13] INTERNATIONAL PRESS TELECOMMUNICATIONS COUNCIL, IPTC PHOTO METADATA WHITE PAPER 2007 8 (2007), http://www.iptc.org/std/photometadata/0.0/documentation/IPTC-PhotoMetadataWhitePaper2007_11.pdf.

[14] *Id.* at 7.

[15] *Id.*

[16] *Id.* at 7-8.

IPTC Core."[17] The proposed schema divides the metadata into four groups: Descriptive, Administrative, Rights, and Technical.[18]

The IPTC White Paper stresses the importance of metadata in connection with commercial images by stating:

> Structured information about image resources such as its name, location, quality and relationship to other objects in the collection is called metadata, and is essential for identifying and managing digital assets such as images. Photographs that do not contain metadata adversely affect everyone working with digital images; resources are wasted, opportunities are lost, liability increases and intellectual property rights are eroded.
>
> . . . .
>
> Widespread use of standardized photo metadata will solve many issues faced by image creators, distributors and users. When contact information for copyright owners and licensors is embedded into digital image files along with other metadata, the process of seeking permissions and correctly attributing images is simplified.[19]

From a legal perspective, the Rights metadata group is the most significant. The Rights metadata standards proposed would include data fields such as creator, credit line and license contact.[20] With the growing 24/7 media presence, news agencies are flooded with photos. The IPTC proposal hopes to avoid copyright and licensing issues that arise from "orphaned" photos.

2. The Cons

On the other hand, hidden metadata can reveal details that the owner wished had remained hidden. In 2003, the British government posted a dossier on Iraq as a Microsoft Word file on

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[17] *Id.* at 7.

[18] *Id.* at 10.

[19] *Id.* at 8.

[20] *Id.* at 12.

their website.[21] Later, a British professor discovered that much of the content was plagiarized.[22] Richard M. Smith, who maintains *computerbytesman.com*, looked below the surface and discovered the revision log for the document, which revealed which members of the government had worked on the plagiarized document.[23] A recent survey of the website for 10 Downing Street did not reveal a single Microsoft Word document; everything now appears to be posted in PDF format.

Another instance of metadata exposing supposedly hidden motives occurred in 2004. The SCO Group filed a lawsuit against Daimler Chrysler and AutoZone for violation of the Unix software agreement.[24] CNet obtained a copy of the complaint in Microsoft Word format, which exposed changes SCO's lawyers had made to the document.[25] Notably, the lawsuit was originally drafted against Bank of America and set to be filed in California not Michigan.[26] Other changes revealed venue and jurisdiction questions as well as allegations and remedies that SCO intended to seek against Bank of America but had been removed from the Daimler Chrysler complaint.[27] These revelations came at a time when SCO was making a push to enforce copyrights they possessed under the Linux system. In May 2003, SCO sent a letter to Fortune 1500 companies warning "they could be legally liable for using Linux if they failed to obtain a license from the Utah based company."[28] Although the information revealed in the document was not criminal, it could have undermined SCO's attempt to enforce

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[21] Richard M. Smith, *Microsoft Word Bytes Tony Blair in the Butt,* June 30, 2003 http://www.computerbytesman.com/privacy/blair.htm.

[22] *Id.*

[23] *Id.*

[24] Stephen Shankland, *SCO Suits Target Two Big Linux Users*, CNet News, Mar. 5, 2004, http://www.news.com/SCO-suits-target-two-big-Linux-users/2100-1014_3-5168921.html.

[25] Stephen Shankland & Scott Ard, *Hidden Text Shows SCO Prepped Lawsuit Against BofA*, CNet News, Mar. 18, 2004, http://www.news.com/Hidden-text-shows-SCO-prepped-lawsuit-against-BofA/2100-7344_3-5170073.html.

[26] *Id.*

[27] *Id.*

[28] *Id.*

their Linux copyright.

Windows' new Vista operating system has some new useful features that could become the next metadata disaster. Vista introduced a powerful "Instant Search" feature that searches file names, properties and text contained in a file.[29] File properties are a form of metadata. Standard file properties probably would not cause most people any embarrassment, but Vista allows users to tag files with custom properties for more efficient searches.[30] An article in eWeek warned of the dangers this new enhanced search poses.[31] For instance, a custom label indicating customers sales region is innocent, but a label signifying "good" and "bad" customers could be disastrous.[32] It is only a matter of time before a file with an awkward custom tag gets away from a user.

D. Can Metadata Be Removed?

The process of removing metadata has been dubbed 'scrubbing.' There are a multitude of programs on the market that claim to scrub metadata from documents at a variety of prices, and there are also some do-it-yourself solutions. A Google search reveals Workshare Protect and Payne Consulting Group's Metadata Assistant as well-marketed scrubbing programs for consumers at a retail or enterprise level.[33] Electronic evidence has spawned a new electronic data discovery (EDD) industry. A report showed 2006 commercial EDD industry revenues were up fifty-one percent to $2 billion and expected to grow to $4 billion by 2009.[34] The rapid growth of this industry reflects the growing importance of electronic

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[29] Windows.com, Explore the Features, Search and Organization, http://www.microsoft.com/windows/windows-vista/features/search-and-organization.aspx (last visited May 7, 2009).

[30] *Id.*

[31] Paul F. Roberts, *Windows Vista: Beware of Metadata Slips*, Dec. 23, 2005, http://www.eweek.com/article2/0,1759,1905102,00.asp.

[32] *Id.*

[33] See www.workshare.com and www.payneconsulting.com for more information.

[34] George Socha & Thomas Gelbmann, *EDD Showcase: EDD Hits $2 Billion*, LAW TECH. NEWS, Aug. 2007, at 1.

evidence management and discovery. The report estimated that there were over 580 EDD vendors in the current market, with the top thirty providers collecting the majority of the revenue.[35]

On the other hand, individuals may also utilize do-it-yourself techniques to remove metadata. Users may strip a Word document of metadata by saving the document as a rich text file (RTF) or creating a PDF. As concern has grown over metadata, many software companies have released help and support documents on how to minimize or prevent metadata. Microsoft Word and WordPerfect both have documentation available on their websites.[36]

It is possible and very important to remove metadata and other information from drives and files. A 2002 study, "purchased 158 second-hand hard drives and recovered a plethora of information, from medical correspondence to banking transactions."[37] Another study analyzed discarded disks and "[m]ore than half . . . contained personal and proprietary information . . . [including] evidence of a married woman's affair."[38] Another recent study found "sensitive details of a US military missile air defence system" on a hard drive purchased on eBay.[39] These studies reveal the importance of monitoring electronic information at all stages, even before litigation begins. An improperly discarded computer could actually lead to litigation.

II. METADATA IN THE DISCOVERY PROCESS

As electronic records and evidence have become more prevalent, there has been a movement in recent years to create

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[35] *Id.*

[36] *See supra* notes 5 & 8 and accompanying text.

[37] Matthew Geiger and Lorrie Faith Cranor, *Scrubbing Stubborn Data: An Evaluation of Counter-Forensic Privacy Tools*, IEEE SECURITY AND PRIVACY, Sept./Oct. 2006, at 17.

[38] *Id.*

[39] *Computer Hard Drive Sold on eBay 'had Details of Top Secret U.S. Missile Defence System'*, Daily Mail (U.K.), May 7, 2009, available at http://www.dailymail.co.uk/news/article-1178239/Computer-hard-drive-sold-eBay-details-secret-U-S-missile-defence-system.html# (last visited May 7, 2009).

new discovery rules regarding electronic evidence. The Federal Rules of Civil Procedure were revised in December 2006 to address electronic evidence. For example, Rule 26 now specifies that "electronically stored information" is subject to initial disclosure if a party may use it to support its case.[40] Rule 34 now specifies that parties may request the production of electronically stored information.[41]

More importantly, Rule 26(f)[42] and Rule 16,[43] which work together, both address discovery of electronic evidence now. This change is significant, because parties must consider the form in which they would like electronic documents produced to them and by them. The form in which electronic documents are produced has become more vital as metadata has become more prevalent and well known. Counsel must consider what metadata may exist in electronic files and whether it is important to preserve and discover that information. Counsel must also examine the electronic files they plan to produce and determine if embedded metadata may damage their case or their client's reputation.

The Federal Rules of Civil Procedure do not address

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[40] FED. R. CIV. P. 26(a)(1)(B). This rule which addresses initial disclosures specifically states "a copy of, or description by category and location of, all documents, electronically stored information, and tangible things that are in the possession, custody, or control of the party and that the disclosing party may use to support its claims or defenses, unless solely for impeachment." *Id.*

[41] FED. R. CIV. P. 34(a). This rule which addresses the scope of production of documents specifically states:

> Any party may serve on any other party a request (1) to produce and permit the party making the request, or someone acting on the requestor's behalf, to inspect, copy, test, or sample any designated documents or electronically stored information *including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained* translated, if necessary, by the respondent into reasonably usable form . . . .

Id. (emphasis added).

[42] FED. R. CIV. P. 26(f)(3). This rule instructs parties to develop a proposed discovery plan addressing several issues including those "relating to disclosure or discovery of electronically stored information, including the form or forms in which it should be produced." *Id.*

[43] FED. R. CIV. P. 16(b)(4). This rule allows the magistrate judges to include a "provisions for disclosure or discovery of electronically stored information" in the scheduling order. *Id.*

metadata specifically, and courts do not agree on how to handle its discovery. As the Federal Judicial Center said, "[s]ome aspects of ESI have no counterpart in print media, metadata being the most obvious. Metadata, which most computer users never see, provide information about an electronic file . . . ."[44] In fact, several commentators have likened metadata to invisible ink, since you never see this information unless you go behind the scenes. A hard-copy document is not going to come with a list of the last ten contributors, all the rough drafts, or a list of everyone who has received a copy in the mail. Nor is a printed picture going to tell you the camera that took the picture, the 'owner,' or the date taken. The unique and multi-faceted nature of metadata and its proliferation has probably hindered the development of one unified rule regarding discovery of metadata.

A. Differing Opinions

With the emerging importance of metadata in litigation in recent years, whether discovery of metadata is allowed and how that may be accomplished has become a question. Many Federal District Courts have addressed the prospect of metadata discovery requests with varying results. The following series provides a survey decisions handed down on the issue.

(i) *In re* Verisign Securities Litigation:[45] The court originally ordered Verisign to produce documents in electronic form and explicitly stated "[p]roduction of TIFF version alone is not sufficient . . . [t]he electronic version must include metadata as well as be searchable."[46] After Verisign objected, the Magistrate Judge clarified his position and ordered the electronic documents produced "in the original format, as it was

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[44] MANAGING DISCOVERY OF ELECTRONIC INFORMATION, *supra* note 1, at 3.

[45] *In re* Verisign Sec. Litig., No. C 02-02270 JW, 2004 WL 2445243 (N.D.Cal. Mar. 10, 2004).

[46] *Id.* at *1. The term TIFF refers to a 'Tagged Image File Format,' which is "[a] widely used and supported graphic file formats for storing bit-mapped images, with many different compression formats and resolutions." SEDONA CONFERENCE GLOSSARY, *supra* note 7, at 51.

kept in the usual course of business."[47] The District Court affirmed the Magistrate Judge's discovery order.

(ii) Williams v. Sprint/United Management Company:[48] In this case, the court ordered Sprint/United to produce spreadsheets in the 'active file' version of Excel.[49] Sprint/United had been producing the spreadsheets in TIFF format, but the plaintiff requested the 'active' format to perform statistical analysis without re-keying in the data.[50] Sprint/United delivered the requested spreadsheet in Excel format after two court orders.[51] However, the files had been scrubbed of all metadata and the cells had been locked.[52] After hearing arguments from both sides, the court ordered Sprint/United to show cause why they should not be sanctioned since previous orders asked "the electronic data be produced in the manner in which it is maintained, and to [the judge] that did not allow for the scrubbing of metadata . . . ."[53]

Sprint/United's main argument was that "emerging standards of electronic discovery articulate a presumption against the production of metadata."[54] After an in-depth discussion, the court formulated this standard:

> [W]hen a party is ordered to produce electronic documents as they are maintained in the ordinary course of business, the producing party should produce the electronic documents with their metadata intact, unless that party timely objects to production of metadata, the parties agree that the metadata should not be produced, or the producing party requests a protective order.[55]

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[47] *In re Verisign Sec. Litig.*, 2004 WL 2445243, at *1.

[48] Williams v. Sprint/United Mgmt. Co., 230 F.R.D. 640 (D.Kan. 2005).

[49] *Id.* at 644.

[50] *Id.* at 642.

[51] *Id.* at 644.

[52] *Id.*

[53] *Id.*

[54] *Id.* at 645-46.

[55] *Id.* at 652 (footnote omitted). The court noted this "same principle may apply when a party requests electronic documents be produced as they are maintained in the ordinary course of business, as an 'active file,' or in their 'native format.'" *Id.* at 652 n.69.

The court contended that this standard correctly places the burden on the producing party, who already has access to the files and is in the best position to determine whether the metadata is objectionable.[56]

Sprint/United also argued the plaintiff did not specifically request the metadata. The court held Sprint/United "should have reasonably understood that the Court expected and intended for Defendant to produce the spreadsheets' metadata . . . ."[57] This holding suggests requests or orders for electronic documents as maintained in the ordinary course of business automatically includes the metadata ordinarily maintained.

(iii) *In re* Priceline.com Inc. Securities Litigation:[58] In this action, Priceline and the plaintiffs disagreed about how electronic files should be produced. The concerns were due to the volume of electronic evidence and the time and cost involved in extracting, reviewing and producing it. The court held that Priceline could produce the files in TIFF or PDF format because it was "the most secure format for the production of documents in this case."[59] However, the order also instructed Priceline to "produce searchable metadata databases, and . . . maintain the original data itself in native format for the duration of the litigation."[60]

(iv) Hagenbuch v. 3B6 Sistemi Elettronici Industriali:[61] After inspecting documents and electronic files in 3B6's office, the plaintiff designated certain files for copying and requested the electronic files in the original format.[62] 3B6 refused this request and produced the files in TIFF format instead.[63] The plaintiff argued the TIFF files were inadequate duplicates of the

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[56] *Id.* at 652.

[57] *Id.* at 654.

[58] *In re* Priceline.com Inc. Sec. Litig., 233 F.R.D. 88 (D.Conn. 2005).

[59] *Id.* at 91.

[60] *Id.*

[61] Hagenbuch v. 3B6 Sistemi Elettronici Industriali, No. 04 C 3109, 2006 WL 665005 (N.D.Ill. Mar. 8, 2006).

[62] *Id.* at *1.

[63] *Id.*

originals for several reasons including that they "lack metadata that track when a document was created or modified and whether emails contained attachments and to whom they were sent"[64] and "make it impossible for Plaintiff to use search terms to quickly and efficiently search through the documents electronically."[65] 3B6 argued the missing information was irrelevant and the TIFF format facilitated Bates numbering of the documents.[66] Unpersuaded by this argument, the court found the missing information was relevant to the plaintiff's desire to piece together a chronology of events and Bates numbering could be achieved in a number of other ways.[67]

(v) Kentucky Speedway, LLC v. NASCAR, Inc.:[68] Kentucky Speedway sought an order to compel the defendants to produce "metadata concerning author and document creation information"[69] by relying on the holding in *Williams*. The court found this argument unpersuasive, and instead held that a showing of particularized need for metadata was required since "[i]n most cases . . . , metadata does not provide relevant information."[70]

(vi) Michigan First Credit Union v. Cumis Insurance Company:[71] The issue in this case was whether Cumis violated the court's order to produce electronic documents by providing the documents in PDF format, which does not include metadata, instead of "native" format. Cumis objected when the plaintiffs originally requested the documents be produced "as they are maintained in the ordinary course of business in their 'native format,' along with intact metadata."[72] Cumis argued that they maintained documents produced by Microsoft Office in paper

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[64] *Id.* at *2.

[65] *Id.*

[66] *Id.* at *3.

[67] *Id.* at *3-4.

[68] Ky. Speedway, LLC v. NASCAR, Inc., No. 05-138-WOB, 2006 WL 5097354 (E.D.Ky. Dec. 18, 2006).

[69] *Id.* at *5.

[70] *Id.* at *8.

[71] Mich. First Credit Union v. Cumis Ins. Soc'y, Inc., No. 05-74423, 2007 WL 4098213 (E.D.Mich. Nov. 16, 2007).

[72] *Id.* at *1.

form and producing the metadata would be costly. The court held given the "relative lack of worth of metadata, and the lack of any showing by Plaintiff that the metadata underlying Microsoft Office documents would be likely to lead to the discovery of relevant evidence . . . production of this metadata would be overly burdensome with no corresponding evidentiary value."[73] Further, the court held the original order did not address metadata, so Cumis could not have violated the order by not producing it.[74]

B. Factors to Consider

This series of cases establishes some factors that both sides should consider. First, the possible relevance of the metadata to the action is very important. The stronger the possibility that the metadata will either lead to admissible information or itself be admissible, the more likely the court will find it discoverable. Next, the time and financial burden of uncovering the metadata is also important. Courts will weigh the possible probative value of the metadata against the burden placed on the producing party. Finally, whether the metadata facilitates the usefulness of the electronic evidence may also play into a court's decision. This factor is the converse of the previous factor, because it relates to the burden on the requesting party as opposed to the producing party. In cases that involve voluminous amounts of electronic documents, removing the metadata can reduce the efficiency with which the requesting party may search and cull the documents. Although none of the decisions discussed turned on this last factor, many of them raised this issue and The Sedona Principles recommend this factor be considered.[75]

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[73] *Id.* at *3.

[74] *Id.*

[75] THE SEDONA PRINCIPLES, *supra* note 3, at 60. Principle 12 states:

> Absent party agreement or court order specifying the form or forms of production, production should be made in the form or forms in which the information is ordinarily maintained or in a reasonably usable form, taking into account the need to produce reasonably accessible metadata that will enable the receiving party to have the same ability to access, search, and display the information as the producing party where appropriate or necessary

The court in the *Cumis* case did not require the production of metadata. At first blush, this decision does not seem congruent with the other decisions. However, the court followed the principal set forth in the *Williams* case.[76] The producing party bore the burden of proving that the production of the metadata was objectionable. If the *Williams* principal is adopted, the question then becomes what makes production of metadata objectionable and how can the opposing party overcome this objection

C. Implications

In light of the discovery issues surrounding metadata and this series of decisions, the question raised is what to advise clients. The trend indicates that a request for electronically stored information produced in the manner ordinarily maintained raises a presumption that metadata will also be produced. A producing party may raise objections and hope the court allows them to suppress the metadata. On the other hand, if the metadata is not ordinarily maintained a party would be able to show that it has no duty to disclose information it does not have. For this reason, some companies have already begun utilizing software that scrubs metadata from files on a regular basis. Parties may also consider archiving files in PDF format, which eliminates the majority of metadata.

III. ADMISSIBILITY OF METADATA

The discoverability of electronic evidence has been a hot topic in the last couple of years and resulted in the new Rules of

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in light of the nature of the information and the needs of the case.

Id. Further, comment 12a on metadata says:

> Aside from its potential relation to the facts of the case, metadata may also play a functional role in the usability of electronically stored information. For example, system metadata may allow for the quick and efficient sorting of a multitude of files by virtue of the dates or other information captured in metadata. In addition, application metadata may be critical to allow the functioning of routines within the file, such as cell formulae in spreadsheets.

Id.

[76] *See supra* note 55 and accompanying text.

Civil Procedure enacted in December 2006.[77] As electronic evidence has become more abundant and accessible, new issues regarding admissibility of this evidence have also arisen. Although this has presented some unique challenges, courts have concluded the Rules of Evidence are generally sufficient for electronic and paper evidence because they are written broadly. The most prominent change appears in Federal Rule of Evidence 901(b)(9), which illustrates how to authenticate a process or system.[78]

Metadata is unique in the world of evidence. Courts rarely see invisible ink admitted to trial. According to a Federal Judicial Center publication, "[s]ome aspects of ESI have no counterpart in print media, metadata being the most obvious."[79] As different electronic media has made its way into the courtroom, comparisons to print media have paved the way for determining admissibility. However, metadata admissibility is a complex question, because computer data is volatile and metadata is created and attached to documents in different ways.

A. The Lorraine v. Markel *Blueprint Applied to Metadata*

In *Lorraine v. Markel,* a June 2007 Maryland District Court opinion, United States Chief Magistrate Judge Paul W. Grimm provided extensive guidance on the issues associated with admissibility of electronic evidence.[80] His opinion laid out the following five-step blueprint to determine whether electronically stored information (ESI) is admissible:

> (1) is the ESI relevant as determined by Rule 401 . . . ; (2) if relevant . . . , is it authentic as required by Rule 901(a) . . . ; (3) if the ESI is offered for its substantive truth, is it hearsay . . . , and if so, is it covered by an applicable exception . . . ; (4) is the form of the ESI that is being offered as evidence an original or

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[77] Lorraine v. Markel Am. Ins. Co., 241 F.R.D. 534, 537 (D.Md. 2007).

[78] FED. R. EVID. 901(b)(9) states, "Evidence describing a process or system used to produce a result and showing that the process or system produces an accurate result."

[79] MANAGING DISCOVERY OF ELECTRONIC INFORMATION, *supra* note 1, at 3.

[80] Lorraine v. Markel Am. Ins. Co., 241 F.R.D. 534 (D.Md 2007).

> duplicate under the original writing rule, or (sic) if not, is there admissible secondary evidence to prove the content of the ESI . . . ; and (5) is the probative value of the ESI substantially outweighed by the danger of unfair prejudice or one of the other factors identified by Rule 403, such that it should be excluded despite its relevance.[81]

The following discussion will briefly review Judge Grimm's admissibility blueprint for electronic evidence and its applicability to metadata.

1. Relevance

Federal Rules of Evidence 401 defines relevant evidence as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."[82] This definition creates a low burden of proof on the party seeking to admit evidence. However, Judge Grimm cautions attorneys to consider and clearly articulate all the potential purposes for the evidence in case it is challenged.[83] Identifying multiple grounds for relevancy rather than relying on one argument gives a judge multiple grounds to consider and a better chance that the evidence will be admitted.[84]

Can metadata ever be relevant? Since the term metadata encompasses such a large and diverse amount of data, it is safe to assume metadata will be relevant in some cases. For example, digital photo metadata from a child pornography case may show the camera model used to take the photos. This information is easily shown to be relevant if the suspect has the same model camera in his possession. Also, as illustrated in the *Hagenbuch* case, date and time stamps on files can be relevant to establish a timeline of events.

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[81] *Id.* at 538.

[82] FED R. EVID. 401.

[83] *Lorraine*, 241 F.R.D. at 541.

[84] *Id.*

2. Authentication

Generally, a party may satisfy authentication with a prima facie showing of "evidence sufficient to support a finding that the matter in question is what its proponent claims."[85] Judge Grimm contends that although this "is not a particularly high barrier to overcome . . . , counsel often fail to meet even this minimal showing when attempting to introduce ESI . . . ."[86] He refers to this as a self-inflicted injury, which may be avoided with preparation.[87]

Due to the nature of electronically stored information, people are more suspicious of its authenticity than they would be of hard-copy documents. For example, compare e-mails to written letters. Although a written letter may be forged, it takes time and skill to convincingly forge another person's handwriting and signature. An e-mail, on the other hand, can easily be forged by a person who obtains a user password or hacks into a computer system. The only challenge this person faces is using a similar linguistic pattern, but the person forging a written letter faces this same challenge.[88]

Despite the additional challenges possibly faced by parties trying to authenticate electronically stored information, the Federal Rules of Evidence have not been altered. The general consensus seems to be that the Rules of Evidence are written in a broad enough manner to accommodate electronically stored information. Federal Rules of Evidence 901(b) illustrates ten non-inclusive methods to authenticate evidence including 901(b)(9) which states "evidence describing a process or system used to produce a result and showing that the process or system produces an accurate result."[89] Of the ten illustrations in the

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[85] FED R. EVID. 901.

[86] *Lorraine*, 241 F.R.D. at 542.

[87] *Id.*

[88] *See* Jim Calloway, *What is Electronic Evidence?*, 28 FAM. ADVOC. 8, 9 (2006) (describing a case where e-mails were fabricated to gain child custody). *See generally* Ross L. Kodner, *Hocus Pocus: Manipulated Digital Evidence How to Spot It*, 28 FAM. ADVOC. 16 (2006) (discussing the challenges in dealing with alteration, destruction or fabrication of digital evidence).

[89] FED R. EVID. 901(b)(9) states, "Evidence describing a process or system used to

rules, this is the one that will normally apply to metadata.

Metadata is a form of computer forensics because it is data that in most instances would not be accessible to the average computer user.[90] Courts have begun requiring a mirror image be created of any drives that are to be examined.[91] This means an "exact copy of an entire storage device" has been made and it allows investigators to inspect the drive without disturbing the original copy.[92] This is especially important if preserving metadata is important. Simply booting up a drive alters 400 to 600 Windows files and ultimately the metadata on a drive.[93] Due to the technical nature of this process, an expert is usually needed to explain the mirroring process and how the metadata was extracted.[94]

In some cases, a non-expert witness with *knowledge* may also be able to authenticate metadata like the type created by a computer user or normally generated by a system or software program. Whether the content of the metadata is accurate will be addressed in step five.

3. Hearsay/Exceptions

Hearsay is one way to have evidence excluded, however there are many exceptions that may allow evidence that is technically hearsay in at trial. "Hearsay" is a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted.[95] While hearsay can have many intricacies, this section will focus on the definition of 'statement' and whether

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produce a result and showing that the process or system produces an accurate result."

[90] Leah Voigt Romano, Comment, *Electronic Evidence and the Federal Rules*, 38 Loy. L. A. L. Rev. 1745, 1756 (2005).

[91] *Id.* at 1759.

[92] Alec Yasinsac et. al, *Computer Forensics Education*, IEEE SECURITY AND PRIVACY, July/Aug. 2003, at 18.

[93] Laura W. Morgan, *Gotcha! Finding the Stuff you Just Know They're Hiding*, 28 FAM. ADVOC. 10, 11 (2006).

[94] *See* Romano, *supra* note 78, at 1762-65. *See generally* Gregory P. Joseph, *Computer Evidence*, 22 LITIGATION 13 (1995) (presenting a overview of authentication issues related to computer evidence generally).

[95] FED R. EVID. 801(c).

the evidence is "offered to prove the truth of the matter asserted."

Rule 801(a) defines "statement" as "(1) an oral or written assertion or (2) nonverbal conduct of a person, if it is intended by the person as an assertion."[96] Since a statement must "be intended by the person as an assertion," many forms of electronic evidence fall outside of the hearsay rule. The content of an e-mail, chatroom transcript or a word-processing document may be considered hearsay since these forms are akin to the spoken word or a handwritten note. Metadata, however, will rarely fall into this definition of statement. First, most metadata is generated by a computer and not a person. Second, metadata is typically a descriptive data type rather than assertive. For example, the date, time-stamp and IP address associated with an e-mail are descriptive elements that are useful to a user, but they do not assert any information. Finally, a person must *intend* for the information in the metadata field to be assertive. Since metadata is normally incidental to the main work, which it describes, the information is rarely going to be seen as intended by a person.

The evidence must also be "offered to prove the truth of the matter asserted" to be considered hearsay. In *Lorraine*, Judge Grimm highlights the advisory committee notes to Rule 801(c), which stated, "If the significance of an offered statement lies solely in the fact that it was made, no issue is raised as to the truth of anything asserted, and the statement is not hearsay."[97] In one case highlighted in the *Lorraine* opinion, an "e-mail between defendant and co-worker [was] not hearsay because [it was] not offered to prove the truth of the substantive content, but instead to show that a relationship existed . . . and it was customary for them to communicate by e-mail."[98] Since technology continues to evolve and grow, this is an important element to keep in mind and argue if trying to admit metadata.

The nature of metadata makes it unlikely that the hearsay

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[96] FED R. EVID. 801(a).

[97] *Lorraine*, 241 F.R.D. at 565.

[98] *Id.* at 566.

rule will apply to it. In the odd case where metadata does constitute hearsay, there are many hearsay exceptions,[99] which may allow metadata in at trial.

4. Original Writing/Duplicate

The fourth step of the admissibility process highlighted by Judge Grimm is the Original Writing rule. Generally, the original writing is required, but a duplicate is admissible to the same extent as an original "unless (1) a genuine question is raised as to the authenticity of the original or (2) in the circumstances it would be unfair to admit the duplicate in lieu of the original."[100] This rule does not affect metadata directly. This speaks more to the way the electronic data was seized in the first place. Parties should do several key things to preserve the integrity of their electronically stored information. First, they should protect the original information by accessing it as little as possible and using a proven technique to make clean copies. Multiple clean copies of the original should be made to prevent having to go back to the original files. Finally, the process used to protect the original and create the duplicates should be documented for trial.

5. Probative Value v. Unfair Prejudice

Balancing the probative value of the evidence against any unfair prejudice is the final step in Judge Grimm's admissibility blueprint. This area is governed by Rule 403, which states, "[a]lthough relevant, evidence may be excluded if its probative value is substantially out-weighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."[101] In his discussion, Judge Grimm draws attention to four circumstances when he thinks courts are likely to consider whether the admission of electronic

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[99] *See* FED R. EVID. 801(d), 803, 804 & 807.

[100] FED R. EVID. 1003.

[101] FED R. EVID. 403.

evidence would be unduly prejudicial.[102] This section will focus on the two circumstances that most likely apply to metadata.

In the first circumstance, Judge Grimm suggests "[w]hen the evidence . . . contains offensive or highly derogatory language that may provoke emotional response" it may be excluded.[103] This could possibly apply to metadata. Although most metadata is innocuous, there could be instances where the content could fall into this circumstance. The most likely scenario where this would occur is in the tracked changes or version feature in Microsoft Word or the comments and hidden text, undo/redo history or document revision annotations features in WordPerfect.[104] These features are similar because they retain information that users have deleted or changed and probably thought no one would see. This creates an opportunity where 'forgotten' metadata may be offensive or highly derogatory.

The second circumstance occurs when "the court is concerned about the reliability or accuracy of the information."[105] This is a more likely issue for metadata. Although metadata can be very useful, it can also be deceptive. For instance, a Microsoft Word document retains a list of the last ten authors.[106] This does not mean these people had a hand in writing the final document or that they ever saw it. The person may have created a template that a later user altered or another user may have accessed the file from their computer. The Sedona Principles say "[c]are should be taken when using metadata, as the content of a given piece of metadata may convey information that is contextually inaccurate."[107] This issue may actually be the hardest to overcome when seeking to admit metadata.

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[102] *Lorraine*, 241 F.R.D. at 584.

[103] *Id.*

[104] *See supra* notes 5 & 8 and accompanying text.

[105] *Lorraine*, 241 F.R.D. at 584.

[106] *See supra* note 5 and accompanying text.

[107] THE SEDONA PRINCIPLES, *supra* note 3, at 60.

IV. Conclusion

Metadata, as modern day electronic invisible ink, will provide new opportunities and obstacles for attorneys as it evolves and grows. There are several points to remember about metadata. First, despite some of its useful characteristics, metadata can be problematic. For this reason, every attorney should be aware of metadata and apprise clients of issues metadata may create or solve before litigation is anticipated. Next, since electronic discovery is becoming more prevalent, the discovery and production of metadata should be considered by both parties. Many factors may affect whether a party is compelled to produce metadata. Also some courts may find production of metadata is implied, while others may require an explicit request. Finally, metadata will be admissible in court if it overcomes the evidentiary hurdles discussed. The biggest hurdles for admissibility will be authenticity and accuracy of the information relayed by the metadata.

Despite the unique and multi-faceted characteristics of metadata, it is discoverable and admissible in our legal system like any other evidence, hard copy or electronic, but it presents new challenges to clients, attorneys and courts.

Gretchen J. Harris

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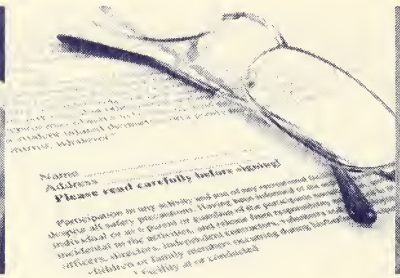

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